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Guideline for establishing or improving primary and intermediate vaccine stores



WHO

Vaccines and Biologicals

World Health Organization

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Contents

<i>Acknowledgment</i>	v
<i>Glossary</i>	vii
<i>Abbreviations</i>	ix
<i>Preface</i>	x
1. Introduction	1
1.1 Purpose of the guideline	1
1.2 Target readership	2
1.3 Layout of the guideline	2
2. Planning a storage and distribution system	3
2.1 Characteristics of a good storage and distribution system	3
2.2 Design of distribution system	4
2.3 Choosing store locations	6
2.4 Location of primary store	7
2.5 Location of intermediate stores	7
2.6 Private or parastatal storage and distribution	8
3. Estimating vaccine type and quantity	10
3.1 Introduction	10
3.2 The existing situation	10
3.3 Future plans	11
3.4 Calculating vaccine storage requirements	12
4. Choosing refrigeration equipment	20
4.1 Introduction	20
4.2 Refrigeration technologies	20
4.3 Selecting refrigerators and freezers	22
4.4 Refrigerants	24
4.5 Calculating vaccine refrigeration capacity	25
4.6 Refrigerators or cold room? Freezers or freezer room?	28
4.7 Calculating capacity for ice pack freezing	28
4.8 Installing refrigerators and freezers	31
4.9 Prefabricated cold stores	32
4.10 Transportable cold stores	35
4.11 Site-built cold stores	35
4.12 Temperature monitoring and alarm equipment	35
4.13 Climatic factors	39
4.14 Lighting	41

5. Space planning	42
5.1 Planning vaccine stores	42
5.2 Vehicle loading bay	42
5.3 Refrigeration equipment area	43
5.4 Vaccine packing area	43
5.5 Storekeeper's office	47
5.6 Packing materials store	48
5.7 Store for injection equipment and waste management supplies	49
5.8 Spare parts store	50
5.9 Heating and air-conditioning	50
6. Choosing a site	51
7. Building standards	53
8. Power supply	56
8.1 Reliability	56
8.2 Stand-by generators	56
8.3 Voltage stability	57
9. Procurement, commissioning and maintenance of equipment	58
9.1 Procurement	58
9.2 Tender specifications	59
9.3 Spare parts	60
9.4 Commissioning	60
9.5 Training	61
9.6 Maintenance contracts	61
10. Sources of information	63
Annex 1: Improving existing cold stores	65
Annex 2: The "shake test"	66

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Abbreviations

°C	degrees centigrade
A	ampere
AC	alternating current
AD	auto-disable (syringe)
BCG	bacille Calmette-Guérin (tuberculosis vaccine)
CFC	chlorofluorocarbon
cm	centimetre
DT	diphtheria and tetanus toxoids (vaccine)
DTP	diphtheria-tetanus -pertussis (vaccine)
EPI	Expanded Programme on Immunization (WHO)
g	gram
h	hour
HepB	hepatitis B (vaccine)
Hib	<i>Haemophilus influenzae</i> type b (vaccine)
Hz	hertz
IPV	inactivated polio vaccine
kg	kilogram
kN	kilonewtons
kVA	kilovolt-ampere
kW	kilowatts
kWh	kilowatt-hour
l	litre
m	metre
m ²	square metre
m ³	cubic metre
max	maximum
min	minimum
ml	millilitre

mm	millimetre
MMR	mumps–measles–rubella (vaccine)
MR	measles–rubella (vaccine)
NID	national immunization day
OPV	oral polio vaccine
Td	tetanus toxoid and diphtheria (reduced component) (vaccine)
TST	time–steam–temperature (indicator)
TT	tetanus toxoid
UNICEF	United Nations Children’s Fund
V	volt
V&B	Department of Vaccines and Biologicals (WHO)
VVM	vaccine vial monitor
W	watt
WHO	World Health Organization
YF	yellow fever (vaccine)

Glossary

Cold room	a purpose made insulated enclosure fitted with refrigeration equipment which maintains a set temperature above 0°C.
Cold store	a facility where the cold room/freezer room or other refrigeration equipment are located, including a packaging area.
Freezer room	a purpose made insulated enclosure fitted with refrigeration equipment which maintains a set temperature below 0°C.
Grossing factor	the actual internal volume of a cold room/freezer room, refrigerator or freezer, divided by the net volume of vaccine that it can accommodate.
Primary store	a principal or main store that receives vaccine from the supplier.

Preface

The 2002 edition of this document takes account of developments that have occurred during the past seven years. Since work started on the new edition, WHO and UNICEF have jointly begun working on the Cold Store Certification Initiative, for which this guideline is one of the source documents.

Among the changes that have been made are the following:

Generally: Many of the manual worksheets in the previous edition have been revised. Active Excel versions of the worksheets may be found on the CD that accompanies the new edition. Cross-references to other documents have been improved and are also hyperlinked. The duplication of advice between documents has been reduced, e.g. the Model Cold Room Specification in the 1996 edition has been omitted as there is now a new version of the cold room and freezer room specification (*Equipment performance specifications and test procedures E1: Cold rooms and freezer rooms, WHO/V&B/02.33, revision date: 15 November 2002*). The latter document also supersedes the draft specification given in the 2000 edition of the *Product information sheets (WHO/V&B/00.13)*.

- **Section 2:** A section on distribution planning has been introduced and the subsequent sections have been renumbered.
- **Section 3:** Advice on storage temperatures above 0°C has been updated. Reference is made to improved methods for estimating vaccine quantity. The introduction of new vaccines is covered in greater detail than previously.
- **Section 4:** Greater emphasis is placed on protection against cold weather. The information on refrigerants has been updated. Changes have been made to reflect the increasing use of HepB vaccine and other vaccines with freezing points close to 0°C.
- **Section 5:** A subsection on storage requirements for AD syringes has been added. Storage requirements for waste management products are discussed to reflect the increased emphasis on safe injections.
- **Sections 6, 7 and 8:** Minor changes have been made.
- **Section 9:** Minor changes have been made and the references have been updated.
- **Section 10:** This section has been completely updated.
- **Annex 1:** Minor changes have been made.
- **Annex 2:** The cold store loading worksheet has been omitted.

1. Introduction

1.1 Purpose of the guideline

Most countries now have well-established immunization services and a network of vaccine stores. This infrastructure must be capable of responding to change. There is continuing pressure to add new vaccines to the schedule. At the same time, novel injection equipment and vaccine presentations are appearing on the market in response to the need to provide safe injections. Managers of immunization services have to organize staff training and plan for the physical and budgetary implications of these changes. They also have to plan for the routine replacement of equipment so as to ensure that the cold chain remains reliable. This guideline is designed to assist with these activities at the primary and intermediate levels.¹ It should help managers to make decisions on the following matters.

- Choice of store location.
- Choice of refrigeration equipment.
- Site and building selection.
- Space planning.
- Equipment procurement.

This document is not a comprehensive technical guide to all the issues covered, nor is it intended to be a substitute for specialist advice where this is appropriate. Adequate technical advice can be obtained in many instances from other WHO documents and/or from reputable equipment suppliers. However, it is advisable to seek independent technical advice when setting up primary and intermediate stores with large cold stores and comprehensive safety equipment.

Frequent reference is made to certain key documents: the *Product information sheets* that are regularly updated by WHO/UNICEF, and the second edition of *Managing drug supply*, produced by Management Sciences for Health in collaboration with WHO. The *Product Information Sheets* are an essential technical companion to this guideline. *Managing drug supply* provides authoritative guidance on all issues relating to drug procurement, storage and distribution, much of it directly relevant to the more specialized field of vaccine management. In Section 10 these and other key sources are listed. Wherever possible the electronic version of this guideline contains hyperlinks to other web-based documents.

¹ The previous edition referred to the national, regional and district levels of the distribution system. The less specific terms “primary” and “intermediate” are now used. This change maintains consistency with the terminology used in *Managing drug supply* (Section 10, reference 1) and reflects the potential for greater flexibility in the planning of distribution.

1.2 Target readership

The guideline is aimed at senior managers at the national and intermediate levels who are responsible for logistics. It should also be of value to specialists preparing tenders for refrigeration equipment and to building professionals involved in the design of vaccine storage facilities.

1.3 Layout of the guideline

The sections in the guideline follow the general order in which decisions are taken when a vaccine distribution infrastructure is being established.

Section 2 outlines the issues to be considered when a distribution system is being planned.

Section 3 discusses how to estimate vaccine storage needs

Section 4 covers the selection of suitable refrigeration equipment.

Section 5 discusses space planning within the vaccine store, including the space required for the storage of injection and waste disposal equipment and the layout of ancillary spaces such as the vaccine packing area and the storekeeper's office.

Section 6 lists the key factors affecting the selection of a suitable store site.

Section 7 discusses the power supply.

Section 8 discusses building standards.

Section 9 covers the management of the procurement process. This includes the appointment of consultants where appropriate, the specification of and tendering for refrigeration equipment, the coordination of any building works that may be necessary in order to prepare for the installation of such equipment, and the commissioning and maintenance of equipment.

Section 10 lists sources of information and advice.

Annex 1 provides advice on the improvement of cold stores that do not comply with all the recommendations in the guideline.

2. Planning a storage and distribution system

2.1 Characteristics of a good storage and distribution system²

A well-run vaccine storage and distribution system should:

- maintain a constant supply of vaccine, injection equipment and waste management supplies;
- keep vaccines, injection equipment and waste management supplies in good condition;
- minimize vaccine wastage attributable to spoilage and expiry;
- maintain accurate inventory records;
- rationalize the locations where vaccine and other supplies are stored;
- use available transport as efficiently as possible;
- ensure safe disposal of used injection equipment, discarded vials and other toxic and hazardous waste generated by the distribution system;
- eliminate theft and fraud;
- monitor the performance of the storage and distribution system;
- provide information that will help with the forecasting of vaccine and other supplies requirements.

A good distribution system is *cost-effective*. This requires systematic cost-effectiveness analysis and operational planning. Once the system is in place, regular performance monitoring is needed in order to ensure that it functions as intended and can adapt to changing circumstances.

When a vaccine distribution system is being planned the main decisions concern the degree of centralization and the number of storage points through which the vaccine will pass before being delivered to the recipient. These decisions are largely determined by political and organizational factors (e.g. issues of regional autonomy); geographical factors (climate, travel distances, etc.); infrastructure (roads, electricity supply, etc.); and the way in which the population is distributed. In a typical central supply model, vaccine procurement and distribution are coordinated at the primary

² The following paragraphs are closely based on Chapter 21 of *Managing drug supply*, Management Sciences for Health, Kumarian Press, USA, 1997. Permission to adapt this material is gratefully acknowledged.

level. Vaccines received at the central medical stores are distributed to intermediate stores and then to service points. In a decentralized system the intermediate stores are responsible for receiving, storing and distributing vaccines; in some cases they may also be responsible for procurement.

1. In designing or redesigning a vaccine distribution system it is necessary to:
 - a) determine how and to what extent it is to be integrated into the national drug distribution system;
 - b) determine the number of storage levels in the system;
 - c) determine the locations of storage sites;
 - d) determine the level of the vaccine supply system at which ordering decisions are to be made;
 - e) fix resupply intervals or the frequency of placing orders;
 - f) select a method of distributing vaccines to service points;
 - g) develop a set of feasible and economic delivery routes and work out a practical delivery schedule to service them;
 - h) estimate operating costs and assess the cost-effectiveness of contracting out for storage and transport at one or more levels;
 - i) determine the key indicators to be used for monitoring performance.

2.2 Design of distribution system

A vaccine distribution system typically requires three or four layers of stores, each with a distinct function.

In a *three-level* distribution system, vaccine is received from the supplier at one or more *primary* stores. Primary stores generally serve an entire country or region; they may also supply service points directly. The capacity of the store is therefore determined by national or regional demand for vaccines and by the frequency with which the store is resupplied. In some countries the primary level has been eliminated and there is direct delivery from the vaccine suppliers to the lower-level stores.

Vaccines are distributed from the primary store to *intermediate* stores, which distribute to *service points*. These are generally *health facility* stores. The size of an intermediate store is determined by the demand from the service points and the frequency with which it is resupplied by the primary store. An intermediate store may be independent but is often on the site of a regional or district hospital.

Sometimes first-level intermediate stores supply second-level intermediate stores. In order to determine the optimum number of levels it is necessary to consider geographical factors, population distribution, the availability of storage space in convenient locations, of trained staff and of transport facilities, and political and other constraints on resources.

Three-level systems tend to be easier to manage and may be less expensive to establish and operate. The value of the stock held is often lower in a three-level system than in a four-level system. However, if health facilities are widely dispersed and travel times are long, a four-level system may provide better service and may even be cheaper to operate. Clearly, it is desirable to design a system that ensures the delivery of vaccine from supplier to child as rapidly as possible. The longer the vaccine remains in the distribution system, especially at the intermediate and lower levels, the greater is the risk that it will lose potency as a result of cold chain failure. The ideal vaccine distribution system produces the shortest possible cold chain operating at the lowest possible cost. However, other issues may override simple considerations of physical planning.

Table 1 indicates the management functions, management activities, supplies and equipment needed for an effective cold chain under a four-level system. Level 3 would be omitted in a three-level system.

In order to achieve a well-designed distribution network the following steps should be taken.

1. Draw a diagram of the existing distribution network. Include all clinical and storage facilities and the supply lines connecting them. Show travel distances and travel times between each store and all the lower-level facilities that it supplies. For each route, establish what method of transport is used, who is responsible for operating and maintaining the transport, and whether the transport is currently serviceable or unserviceable. This information gives a good picture of the status of the distribution system and shows where problems are located.
2. Draw diagrams of three or four alternative arrangements. Include alternatives based on different linkages between existing facilities as well as alternatives requiring additional facilities. Consider how each alternative could fit into the general drug distribution system. The efficient use of the limited available transport is an important consideration in developing countries and the maintenance of separate vertical transport programmes is difficult to justify, especially at the peripheral level. Estimate the costs of operating each alternative system. Make a final choice on the basis of both the estimated operating costs and the ability to respond to vehicle breakdowns and other eventualities. For example, a system relying on a distribution round using a refrigerated vehicle can work well in a country with good roads and a good maintenance infrastructure but is unlikely to survive long in a country where the infrastructure is poor.
3. Consider alternative supply intervals. Short supply intervals reduce the risk of stockouts and reduce the required capacity of cold chain equipment, but they increase transport costs. Longer supply intervals reduce transport costs but increase the required capacity of cold chain equipment, the value of vaccines held in the system and the cost of vaccine wastage in the event of a cold chain failure.³

³ Refer to Chapter 15 of *Managing drug supply* for a full discussion of inventory management.

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4. For each alternative, estimate the total cost of operating the system. Include the initial purchase cost of vaccine and the costs of storing the vaccine (wastage, store operating costs, etc.), transporting it (vehicle purchase and running costs, fuel, etc.) and managing the system (administration, communications, etc.). A proportion of these costs is variable (e.g. supply costs) and a proportion is fixed (e.g. salaries and building maintenance). One way of modelling them is to use the *total variable cost analysis* method.⁴
 5. Select and implement the system that provides the service of best quality which is compatible with the available funds.

2.3 Choosing store locations

The geographical distribution of population and health facilities determines where vaccines are needed. The location of in-country manufacturing facilities and international airports determines where the primary storage points should be located. Intermediate stores are located at convenient places between these two sets of points. Storage planning starts with an analysis of existing and future supply requirements in order to establish the quantity of vaccines needed by each facility and the overall volume to be handled by the distribution system.

1. Create a map of vaccine demand

Map the geographical distribution of vaccine demand. Where are the hospitals, health clinics and other service points? Which ones serve the largest numbers of people? Where are new or expanded facilities likely to be located? Estimate the volume and weight of each facility's annual vaccine requirement.

2. Select primary storage points

Many smaller countries have only one international airport capable of receiving vaccine shipments. Larger countries, however, often have several suitable airports. Some countries also have indigenous vaccine manufacturers. Multiple primary storage points may be justified in large countries or where physical barriers exist, such as mountain ranges or rivers without bridges.

3. Plan primary distribution routes and locate intermediate stores

Intermediate stores are best located on all-weather roads or close to airports. It is essential to have good transport routes linking primary and intermediate stores. These routes handle the largest volumes of vaccines and must be reliable. Travel distances must be planned to take account of the cold life of the transport boxes, leaving an adequate margin for unforeseen delays. Where practicable, a delivery circuit with more than one drop-off point can significantly reduce transport costs.

⁴ Refer to Chapter 41 of *Managing drug supply* for an explanation of this methodology.

4. Plan secondary distribution routes

The planning of secondary distribution routes requires detailed knowledge of rural road conditions, travel times and available transport. Consult local staff because their knowledge is essential.

5. Size the stores

Use the procedures described in this guideline to plan requirements for equipment and space in each store. Always provide spare capacity in order to allow for emergencies and programme expansion.

2.4 Location of primary store

Vaccines received from overseas must be cleared through customs as rapidly as possible. In many countries the health ministry collects vaccine from an airport when it arrives.

If most vaccine is received from overseas by air the primary store should be situated close to the international airport where the vaccine arrives.

It is logical for the primary store to be located within the central medical stores. However, this may involve some loss of administrative control. It is essential that the staff of central medical stores are properly trained in the management of vaccine storage and vaccine handling because they are responsible for looking after a very valuable commodity.

2.5 Location of intermediate stores

The location of intermediate stores is largely determined by administrative, physical and climatic factors.

Administrative factors

Vaccine storage facilities are often located in existing administrative centres. They frequently serve catchment areas that coincide with local government areas. This may not produce an efficient distribution system and may not make good use of scarce human resources. It is important to analyse and consider the alternatives. For example, it might make better sense for one storage facility to serve several administrative districts, provided that any political issues can be resolved.

Physical and climatic factors

The optimal location of regional and district stores depends on the transport network, which may be affected by road closures at certain times of the year.

It often makes sense to locate a regional or district vaccine store in the compound of a regional or district medical store.

2.6 Private or parastatal storage and distribution

So far this section has assumed that government carries out vaccine storage and distribution. If responsibility for storage and distribution is given to a parastatal body or a private company, higher-level EPI management is freed from its direct responsibility for the day-to-day running of the cold chain.

A primary store may not be required if a substantial quantity of vaccine is obtained from a national manufacturer. Instead, it may be more cost-effective for the manufacturer to deliver direct to the intermediate stores. This strategy also shortens the cold chain. Subject to a suitable contractual agreement, the national manufacturer may also be able to store and distribute imported vaccines.

Table 1: Typical requirements for an effective cold chain

Level/staff	Management	Supplies and equipment
<p>Primary (Level 1) Staff functions Primary management:</p> <ul style="list-style-type: none"> National programme coordination Epidemiology Logistics Transport management Training Procurement Budget and finance Data analysis <p>Primary store:</p> <ul style="list-style-type: none"> Storekeeping Delivery <p>Primary maintenance</p>	<p>Programme planning:</p> <ul style="list-style-type: none"> Demographic/epidemiological data Administrative structures Logistics systems <p>Programme monitoring:</p> <ul style="list-style-type: none"> Disease surveillance Immunization coverage Cold chain/transport operation Supplies usage Programme costs <p>Supplies management:</p> <ul style="list-style-type: none"> Vaccine purchase/storage/delivery Refrigeration monitoring Transport management <p>Independent evaluations/certification</p> <p>Staff recruitment and training</p> <p>Supervision of regional operations</p>	<p>Cold chain equipment:</p> <ul style="list-style-type: none"> +5°C cold room -20°C freezer room Ice pack freezers and cold boxes^a Stand-by power supply <p>Working and safety stocks:</p> <ul style="list-style-type: none"> Vaccines Injection equipment Waste management equipment Stationery/forms Cold chain monitor cards Cold chain equipment and spare parts <p>Transport and fuel</p> <p>Special facilities:</p> <ul style="list-style-type: none"> Vaccine control laboratory (if feasible) Central repair workshop
<p>Intermediate (Level 2) Staff functions Level 2 management:</p> <ul style="list-style-type: none"> Regional programme Epidemiology Logistics/transport Training Data analysis/reports <p>Level 2 store:</p> <ul style="list-style-type: none"> Storekeeping Delivery <p>Regional maintenance</p>	<p>Programme monitoring</p> <ul style="list-style-type: none"> Disease surveillance Immunization coverage Cold chain/transport operation Supplies usage <p>Supplies management</p> <ul style="list-style-type: none"> Requisitioning/storage/delivery Refrigeration monitoring Transport management <p>Staff recruitment and training</p> <p>Supervision of district operations</p>	<p>Cold chain equipment:</p> <ul style="list-style-type: none"> +5°C cold room OR refrigerators Vaccine freezers Ice pack freezers and cold boxes^a Stand-by power supply <p>Working and safety stocks:</p> <ul style="list-style-type: none"> Vaccines Injection equipment Waste management supplies Stationery/forms Spare parts <p>Transport and fuel</p>
<p>Intermediate (Level 3)^b Staff functions Level 3 management:</p> <ul style="list-style-type: none"> District programme Data analysis/reports <p>Level 3 store:</p> <ul style="list-style-type: none"> Storekeeping Delivery <p>District maintenance</p>	<p>Programme monitoring:</p> <ul style="list-style-type: none"> Disease reporting Immunization reporting Cold chain/transport operation Supplies usage <p>Supplies management:</p> <ul style="list-style-type: none"> Requisitioning/storage/delivery Refrigeration monitoring Transport management <p>Supervision of health facilities</p>	<p>Cold chain equipment:</p> <ul style="list-style-type: none"> Vaccine refrigerators and freezers Ice pack freezers and cold boxes^a Stand-by power supply <p>Working and safety stocks:</p> <ul style="list-style-type: none"> Vaccines Injection equipment Waste management supplies Stationery/forms Spare parts <p>Transport and fuel</p>
<p>Health facility (Level 4) Staff functions</p> <ul style="list-style-type: none"> Giving immunizations Injection safety Safe disposal Equipment care and maintenance Storekeeping <p>Reporting</p>	<p>Supplies management</p> <ul style="list-style-type: none"> Requisitioning/storage Refrigerator monitoring Transport management <p>Reporting of:</p> <ul style="list-style-type: none"> Disease incidence Immunizations given Equipment defects Transport mileage and defects Stock in hand 	<p>Cold chain equipment</p> <ul style="list-style-type: none"> Vaccine refrigerator + freezer section Cold boxes for outreach sessions Vaccine carriers <p>Working and safety stocks:</p> <ul style="list-style-type: none"> Vaccines Injection equipment Waste management supplies Stationery/forms <p>Transport and fuel</p>

^a UNLESS refrigerated transport is used.

^b This level would not exist in a three-level distribution system.

Adapted from Managing drug supply (Section 10, reference 1), Fig. 23.4.

3. Estimating vaccine type and quantity

3.1 Introduction

Before refrigeration equipment is specified, determine the type and quantity of vaccine to be stored. The first step in this process is to review vaccine consumption and assess future programme requirements. In order to establish realistic data, consult with the people or organizations responsible for programme management, epidemiology, stores management, transport management and finance.

3.2 The existing situation

Review the existing situation with reference to the following matters.

Vaccine type and presentation

- Which vaccines are used?
- What presentations are used?
- What other products that require refrigeration, e.g. rabies vaccine, snakebite sera, and testing kits, are kept in cold storage alongside the vaccines?⁵

Vaccine storage

- Are vaccines being stored at the temperatures recommended by WHO and the manufacturers? (Table 2.)
- Do storage times ever exceed the maximum times recommended by WHO and the manufacturers? (Table 2.)
- What is the maximum stored volume per dose for each vaccine?⁶
- What is the stored volume per dose for diluents, including those stored at ambient temperature?

⁵ Note that insulin should not be stored with vaccines at the primary or intermediate level. If there is only one refrigerator at the service level, insulin vials should be stored in a separate container, clearly marked "INSULIN – keep separated from vaccines".

⁶ Most countries receive individual vaccines from more than one source. The most bulky presentation is the one that should determine vaccine storage requirements. Refer to Table 2 in *Guidelines on the international packaging and shipping of vaccines* (WHO/V&B/01.05). Geneva: WHO; 2001.

Vaccine management

- How many doses of each vaccine are received per annum and in what presentation?
- What is the supply interval for each vaccine?
- What is the reserve stock for each vaccine?

Funding

- What funds are available for improvements in logistics?

Table 2: Recommended temperatures and storage times

	Primary	Intermediate		Health centre	Health post
		Region	District		
	6 months ^a	3 months	1 month	1 month	Daily use
OPV	-15°C to -25°C		+2°C to +8°C		
BCG	WHO no longer recommends that freeze-dried vaccines be stored at -20°C. Storing them at -20°C is not harmful but is unnecessary. Instead, these vaccines should be kept in refrigeration and transported at +2°C to +8°C.				
Measles					
MMR					
MR					
YF					
Hib freeze-dried					
DT					
DTP					
DTP–HepB					
HepB					
Hib liquid					
Td					
TT					
<p><i>Diluent vials must NEVER be frozen. When the manufacturer supplies a freeze-dried vaccine packed together with its diluent, ALWAYS store the product between +2°C and +8°C. Where space permits, diluents supplied separately from the vaccine may be stored safely in the cold chain between +2°C and +8°C.</i></p> <p>^a Six months is the maximum recommended storage time at primary level. This includes the period required to obtain clearance from the national regulatory authority.</p>					

3.3 Future plans

Review future plans with reference to the following matters.

Vaccine type and presentation

- Which vaccines are likely to be added to the schedule in the near future?
- Are the presentations of existing vaccines likely to change in the near future? For example, are there plans to use a single-dose prefill technology, e.g. Uniject.

Vaccine storage

- What plans are there for programme growth, including plans to achieve higher coverage?
- Is storage capacity for growth to be provided immediately or phased in later?

Vaccine management

- Are there any plans to change the supply intervals or the levels of reserve stocks?
- Has the WHO multi-dose vial policy been adopted?⁷ If not, will it be adopted?
- What other plans are there to reduce vaccine wastage?

Assess how these changes would affect the volume of vaccine to be stored. For example, the adoption of single-dose presentations would increase the cold storage volume while a shorter supply interval would reduce storage requirements. The retention of opened vials can greatly reduce vaccine consumption when session sizes are small.

3.4 Calculating vaccine storage requirements

This guideline does not prescribe a method for estimating overall vaccine consumption. Generalized methods often do not give sufficiently accurate results to take account of the many complex factors affecting developed programmes. The accurate calculation of vaccine consumption requires a careful analysis of existing programme data and a consideration of future requirements.

However, once vaccine consumption figures have been established by other means, the step-by-step process described in this section may be used to estimate the physical volume of vaccine to be accommodated.

3.4.1 Estimating annual vaccine quantity

The number of doses of vaccine required has traditionally been calculated on the basis of population, coverage and wastage factor, and has been increased annually in order to allow for programme growth.

Vaccine requirements can also be estimated by using data on the numbers of registered neonates and eligible women per session in each immunization setting (an immunization setting can be a maternity ward, a fixed clinic or an outreach or mobile team session). This information usually has to be collected by direct observation of sessions because, typically, it is not included in the reporting system. An allowance must be added to this estimate for *operational* vaccine losses, which arise because of cold chain failure during transit and storage.

⁷ WHO policy statement: *The use of opened multi-dose vials of vaccine in subsequent immunization sessions* (WHO/V&B/00.09).

In situations where opened vials are disposed of at the end of each session, the session size determines *administrative* wastage. If, for example, a 20-dose vial of DTP is opened, 9 doses are administered and the vial is then discarded, the result is that 11 doses are wasted. However, if opened vials are kept until finished, administrative wastage can be greatly reduced.

In countries where programmes are not well developed it may be impossible to calculate vaccine requirements as described above. The session size may have to be estimated. This can be done with reference to records of the number of neonates registered per facility and to policy on the frequency of sessions.

Alternatively, in the absence of reliable records from facilities, estimates may have to be made on the basis of previous demand, data on which can be derived from stock records. The danger with demand-based estimates is that poor session planning, the choice of inefficient presentations and shortages or gross wastage of vaccine may be perpetuated.

Once the annual number of doses and the presentations are known the annual volume of each vaccine can be calculated. When the delivery interval and the requirement for safety stock are known it becomes possible to calculate the maximum volume of vaccine to be held in stock.

3.4.2 *Estimating storage volume per dose*

The storage volume per dose of vaccine varies. It is determined by the type of vaccine, the number of doses per vial or ampoule, the physical size of the vial or ampoule and the bulkiness of the external packaging. Donor-dependent countries should ensure that a safe worst-case figure is obtained for each antigen, because the manufacturer of the vaccine may not be known until the shipment arrives.

Two of the most reliable sources of information on vaccine volumes are:

- *Guidelines on the international packaging and shipping of vaccines* (WHO/V&B/01.05). Geneva: WHO; 2001.
- *Vaccine volume calculator* (WHO/V&B/01.27). Available from <http://www.who.int/vaccines-documents/DocsPDF01/www586.pdf>.

In countries where vaccines are purchased, figures should either be based on data obtained from all the manufacturers who regularly supply vaccine or from the latest version of the WHO vaccine volume calculator.

3.4.3 Estimating vaccine storage volume

Review current supply intervals and reserve stock levels before estimating the maximum volume of vaccine to be stored.

1. Supply interval

The supply interval determines how frequently vaccine is delivered to a particular store. Note that the supply interval is not necessarily the same as the order interval. At the primary level, for example, the order for vaccines is often placed annually, whereas the vaccine may be delivered at six-monthly or even three-monthly intervals. However, at the intermediate level the supply interval generally coincides with the order interval.⁸ Reducing the length of the supply interval diminishes the volume of refrigeration equipment required to satisfy a given annual consumption.

2. Working stock level

The working stock is that proportion of the total stock in hand that will satisfy demand between one delivery and the next.

3. Safety stock level

Safety stock (sometimes called reserve stock) ensures that vaccine supplies do not run out when there is a supply delay or an unexpected peak in demand. Unexpected demand may occur if there is an epidemic. There may also be periodic peaks in demand arising from national immunization days or from seasonal campaigns, e.g. immunization sessions in schools. These periodic peaks should be planned for and should not be met from the safety stock.

At all stores, and particularly at primary stores, new orders for vaccine must be placed some time before the safety stock level is reached, because the supplier's lead time has to be taken into account. In the case of an overseas vaccine manufacturer the lead time may be several months. A safety margin should always be added in order to allow for unforeseen delays or sudden accelerations in demand.

Select supply intervals, working stock levels and safety stock levels that are locally appropriate. Higher-level stores generally have longer supply intervals and larger safety stock levels than lower-level stores. Safety stock levels in primary stores are typically set to cover normal consumption for three months. Upper-level intermediate stores typically hold a one-month safety stock, while lower-level intermediate stores and health facilities carry a two-week safety stock.

Consider and balance the following factors.

⁸ For a more detailed discussion of inventory management, refer to the Procurement and Managing Distribution sections of *Managing drug supply*, Management Sciences for Health, Kumarian Press, 1997.

- **Vaccine expiry dates**

Supply and order intervals must be short enough to ensure that all vaccine received at the primary store can be used before it expires.

- **NIDs and campaigns**

Vaccine for NIDs and campaigns is consumed rapidly. Figure 1 indicates how careful phasing of supply dates can avoid the need for extra storage capacity.

- **Financial considerations**

Frequent small deliveries of vaccine increase the costs of administration and internal transport. The effect on air freight charges and port clearance costs should also be considered.

- **Seasonal access**

There may be road closures during the rainy season, affecting access to outlying stores. Accordingly, vaccine stock levels may have to be increased at these stores so as to ensure continuity of supply.

- **Seasonal demand**

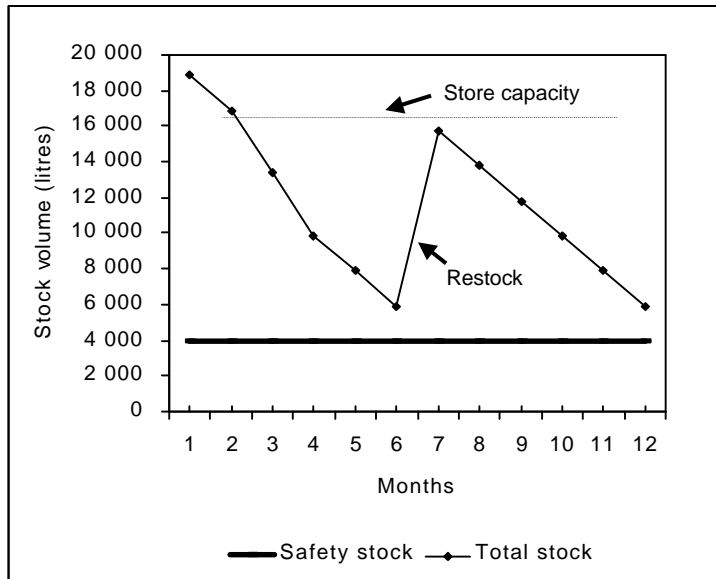
The demand for immunization can fluctuate with the farming cycle and other seasonal factors. Outlying stores should be of a size that accommodates peak demand, NOT average demand.

- **Cold chain reliability**

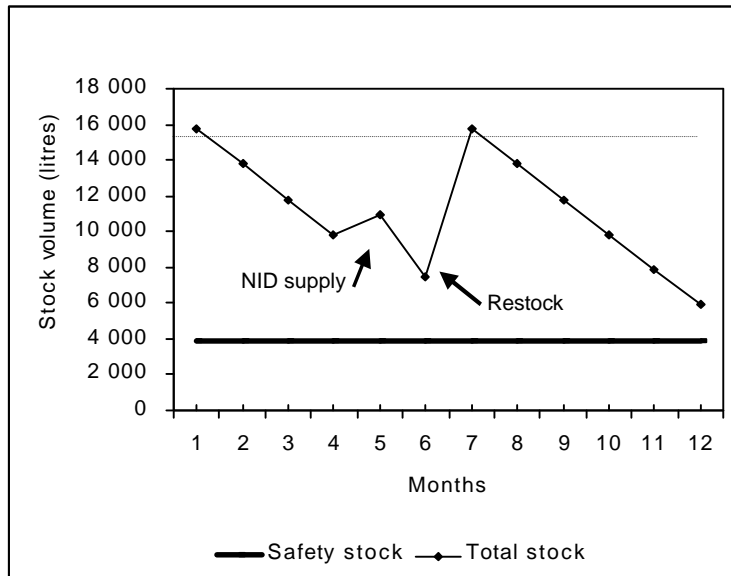
It is unwise to hold large stocks for long periods in stores where mains electricity is unreliable and where fuel supplies for stand-by generators cannot be guaranteed.

The vaccine storage volume is calculated by adding the maximum volume of the working stock to the volume occupied by the safety stock. A safety margin is then added to take account of stock peaks (Figure 2). Stock peaks occur when the volume of vaccine actually distributed in the period between any two supply intervals is less than the volume predicted to be distributed during this period. They can also arise if a vaccine delivery arrives earlier than anticipated. A realistic safety margin can be derived by analysing stock records, which, for example, show past instances of overstocking and understocking caused by seasonal fluctuations in demand, campaigns, NIDs and so forth.

Figure 1: Phasing supply dates

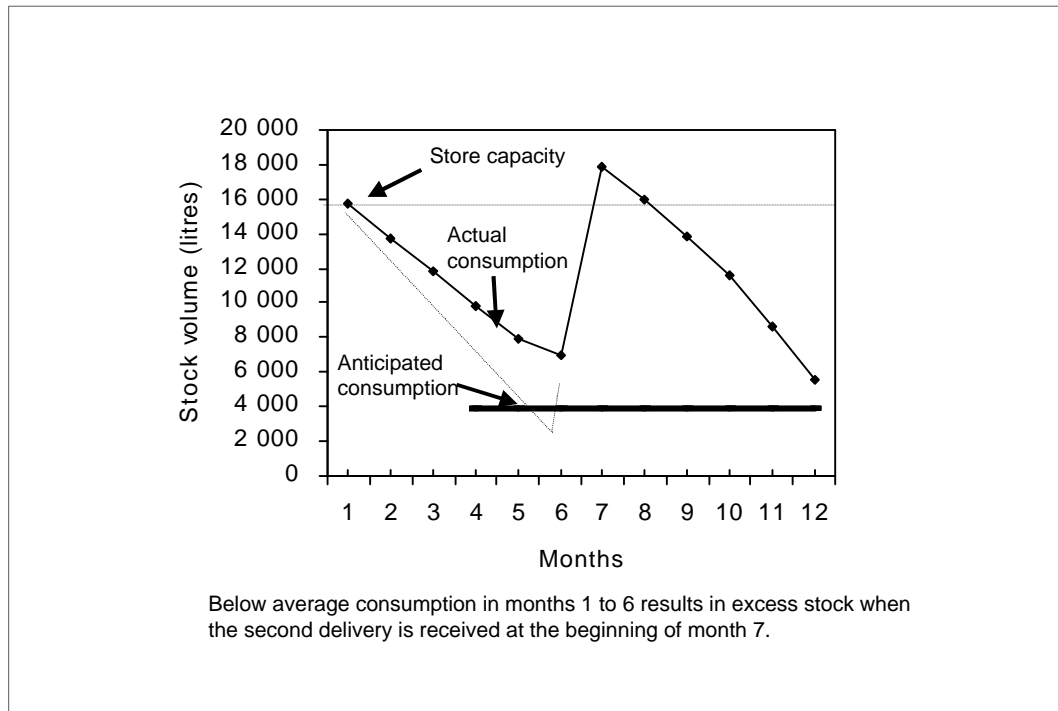


Alternative A - NID vaccines delivered in month 1.
Additional cold store capacity required.



Alternative B - NID vaccines delivered in month 5.
No additional cold store capacity required.

Figure 2: Stock peaks



3.4.4 Diluents and droppers

At the primary and intermediate levels, diluents and OPV droppers are normally stored at ambient temperature. However some presentations include the diluent in the same packaging as the vaccine. In such cases it is necessary to refrigerate the diluent as well as the vaccine at +2°C to +8°C (Table 2). At the health facility all diluents should be refrigerated.

Diluents and droppers should always be kept in the vaccine store. A commonly observed failure of stock control systems is that mismatches occur between vaccine and diluent at all levels in the supply system. Vaccine produced by one manufacturer must *never* be used with diluent produced by another. It is essential that the storekeeper issues each vial of freeze-dried vaccine with an ampoule of diluent of the correct type and preferably from the correct batch. Diluents have expiry dates that do not necessarily match those of the vaccines with which they are used. In general, diluents have a shelf-life of five years. In many cases, therefore, the diluent expiry date is later than that of the corresponding vaccine.

3.4.5 Worksheets

Worksheet 1 may be used to calculate the storage volume of each vaccine. It may also be used to calculate the volume of diluent and OPV droppers. Refer to section 3.4.2.

An MS Excel version of the worksheet is available on the accompanying CD-ROM.

3.4.6 *Volume of insulated vaccine packaging*

Worksheet 1 can also be used to estimate the volume of the manufacturer's insulated shipping containers. This calculation is necessary only in the following cases.

- *Vaccines are stored in cold stores in the shipping containers.* Storing vaccines in this manner greatly increases the size of cold store needed. However, the extra cost may be justifiable at higher-level stores where vaccine is kept alongside other refrigerated pharmaceuticals. In very large cold stores, where goods are stored and moved on pallets, vaccine should be stocked in insulated shipping containers.

The manufacturer's insulated packaging is kept and reused for in-country vaccine shipments.

- Insulated packaging occupies up to eight times the volume of the vaccine that it contains. The boxes cannot be "nested". If they are to be kept, sufficient storage space has to be provided so that they can be stacked.

Three categories of vaccine packaging are used for international air freighting. They are listed below in decreasing order of bulk.

- **Class A packaging** is designed to ensure that the temperature of the vaccine does not rise above +8°C for a minimum exposure of 48 hours at an ambient temperature of 43°C. Class A packaging is only used for transporting OPV.
- **Class B packaging** is designed to ensure that the temperature of the vaccine does not rise above +30°C for a minimum exposure of 48 hours at an ambient temperature of 43°C. It must also prevent the temperature of the vaccine from dropping below +2°C for a minimum of 48 hours at an ambient temperature of -5°C. Class B packaging is used for transporting BCG, DTP (and its combinations with HepB and Hib), Hib liquid, Hib freeze-dried, measles, MR, MMR and YF vaccines.
- **Class C packaging** provides no specific protection against high temperatures. However, it must prevent the temperature of the vaccine from dropping below +2°C for a minimum exposure of 48 hours at an ambient temperature of -5°C. Class C packaging is used for transporting DT, HepB, Td and TT vaccines.

The bulking factors given for the three types in Worksheet 1 are based on an earlier WHO standard. If the packaging volume is critical, obtain accurate dimensions from the vaccine manufacturer.

3.4.7 *Volume of other vaccines and refrigerated products*

Refrigerators, freezers and cold rooms are commonly used to store non-EPI vaccines such as rabies and influenza vaccines, together with other refrigerated products. This must be taken into consideration when equipment is being sized. Information should be obtained from the departments concerned.

Worksheet 1. Vaccine storage volume

Item:				
Storage temperature:	-15 to -25°C <input type="checkbox"/>	+2 to +8°C <input type="checkbox"/>	Ambient <input type="checkbox"/> (tick appropriate box)	
A. Presentation:	doses per vial or ampoule <input type="checkbox"/>		A.	
B. Packaging:	vials or ampoules per pack <input type="checkbox"/>		B.	
<p>Note: For step C, refer to Table 2 of the <i>Guidelines on the international shipping of vaccines</i> (WHO/V&B/01.05) or to the WHO Vaccine volume calculator, http://www.who.int/vaccines-documents/DocsPDF01/www586.pdf. Alternatively, obtain manufacturer's data.</p>				
Enter packed volume per dose				
C. Volume per dose:		= <input type="text"/> cm ³ /dose	C.	
Calculate number of doses required				
D. Total doses/year:	(from analysis of programme records)	= <input type="text"/> doses	D.	
Calculate storage volume				
E. Annual volume:	C <input type="text"/>	x D <input type="text"/>	= <input type="text"/> litres	E.
		1000		
F. Supply interval:	Enter supply frequency in months:	<input type="text"/>	= <input type="text"/> years	F.
		12		
G. Safety stock:	Enter safety stock level in months:	<input type="text"/>	= <input type="text"/> years	G.
		12		
H. Storage volume (litres):	E <input type="text"/>	x (F + G) <input type="text"/>	= <input type="text"/> litres	H.
J. Storage volume (cubic metres):		H <input type="text"/>	= <input type="text"/> m ³	J.
		1000		
K. Transport box bulking factor:	BCF, OPV, measles, MMR, MR	= 6.0	<input type="text"/>	K
(enter value in box K)	Other vaccines	= 3.0		
	Diluent, droppers	= 1.5		
L. Transport box volume:	J <input type="text"/>	x K <input type="text"/>	= <input type="text"/> m ³	L.

Notes:

- 1) Complete one of these worksheets for each vaccine.
- 2) Complete one of these worksheets for each diluent and for the OPV droppers.
- 3) Collect the completed worksheets for each of the three storage temperatures and add up the total storage volume required for each temperature.
- 4) Carry the calculated total volume for each storage temperature to worksheet 2.

4. Choosing refrigeration equipment

4.1 Introduction

Vaccines can be stored in cold rooms, freezer rooms, refrigerators or freezers. They are transported in insulated vaccine carriers or in refrigerated transport vehicles. Vaccine carriers require a supply of ice packs and sufficient refrigeration capacity to freeze them.

Refrigeration and transport equipment should be chosen after considering:

- operational reliability;
- space requirements;
- infrastructure costs;
- equipment purchase costs;
- equipment installation costs;
- running costs;
- replacement costs.

The WHO/UNICEF *Product information sheets* give advice on the selection of equipment. Details are given of refrigerators and freezers that comply with the relevant WHO standards for vaccine storage. There is also a list of cold store manufacturers. The documents are regularly updated and may be obtained from WHO/V&B in Geneva or downloaded from the V&B document centre web site.⁹ They are the primary reference source in this field.

4.2 Refrigeration technologies

Two types of refrigeration cycle are used for vaccine storage: the *compression* cycle and the *absorption* cycle.

⁹ The web site address is <http://www.who.int/vaccines-documents/DoxGen/H3DoxList.htm>

4.2.1 Compression cycle appliances

Compression cycle appliances are the more common and by far the more efficient, delivering approximately four times as much cooling capacity per unit of electricity as equivalent absorption cycle appliances. Most of the larger refrigerators and freezers and all cold rooms and freezer rooms use the compression cycle, which is also used by nearly all photovoltaic solar refrigerator manufacturers. Compression cycle appliances are preferable wherever there is a reliable electricity supply for more than eight hours a day

It is not advisable to purchase kerosene/electric or gas/electric absorption cycle refrigerators for continuous use with electricity.

The holdover time¹⁰ of a compression refrigerator is greatly improved by lining the inside of the cabinet with water-filled tubes or ice packs. The water stays frozen as long as electricity is available. If the supply fails, the ice gradually melts and keeps the cabinet cool. Many ice-lined refrigerators are able to operate indefinitely on eight hours of electricity per day. However, the holdover performance depends on the ice lining being completely frozen when the electricity fails.

Because electricity supplies are rarely completely reliable, the use of ice-lined refrigerators is strongly recommended for bulk vaccine storage on any site, whether or not there is a stand-by generator. All the mains-powered compression refrigerators that currently meet WHO standards are top-loading ice-lined models.

WARNING: Freezing destroys some vaccines, e.g. TT and HepB. They freeze in an ice-lined refrigerator if the thermostat is set to maximum. Even if the thermostat is correctly set the temperature near the bottom of ice-lined refrigerators may drop below 0°C when the ice lining is refrozen after a power failure. Freeze-sensitive vaccines should NOT, therefore, be stored within 20 cm of the base of these models. Some models have a mark inside the cabinet which indicates areas potentially dangerous for the storage of these vaccines. It is essential that staff are properly trained in the use of the equipment and that they understand these problems.

4.2.2 Absorption cycle appliances

The absorption cycle uses a constant heat source to drive the refrigeration cycle. The source may be an electric heater, a gas or kerosene flame, or heat from a solar thermal panel. Absorption appliances do not perform as well as their compressor-driven equivalents and they require constant attention in order to ensure adequate performance for the vaccine cold chain. The principal advantages of the absorption cycle are the absence of moving parts and the possibility of multi-fuel operation. The principal disadvantages are high maintenance costs and poor efficiency. Kerosene units are sensitive to fuel impurities and require frequent burner adjustment and maintenance. Temperature control in models using gas or kerosene is limited and, even on the lowest flame setting, they can freeze TT, DTP and HepB vaccines.

¹⁰ The holdover time is the period during which the temperature of the vaccine is maintained below +10°C in the absence of any power supply and at a given ambient temperature.

Models that combine vaccine storage with ice pack freezing in the same insulated chamber do not control temperature or freeze ice packs as well as models that have separate freezing and vaccine storage compartments.

Absorption refrigerators and freezers are unable to handle large cooling loads. They are therefore best suited for point-of-use refrigeration in health facilities. Nevertheless, they may have to be used for bulk vaccine storage in places where electricity is unavailable.

WARNING: Some vaccines, e.g. HepB, freeze inside an absorption cycle refrigerator if stored close to the evaporator and if the thermostat is set to maximum.

4.2.3 Solar-powered equipment

The use of solar units for vaccine storage can only be justified at present in situations where no alternative fuel source is available. This situation may well arise at the health facility level. It is unlikely to arise at the primary and intermediate levels. Solar refrigerators are expensive to purchase and install. Maintenance has to be carried out by skilled technicians and can be expensive. The batteries generally have to be replaced every five to seven years. Vaccine storage capacity is quite limited for intermediate-level applications, although perfectly satisfactory for health facilities.¹¹

Solar power reviews have stressed the need to integrate solar refrigeration for EPI with other primary health care and community applications. These applications include the lighting of health centres and health workers' homes, the provision of power for radios and televisions, and income-generating applications such as battery-charging. These additional applications should be strongly promoted because they help to create the critical mass needed to support an effective maintenance network.

4.3 Selecting refrigerators and freezers

Wherever local purchasing rules allow, refrigerators and freezers should be chosen from the WHO/UNICEF *Product information sheets*, which give detailed guidance on the choice of equipment. Most of the products listed have been tested by an independent laboratory against the performance criteria laid down in the WHO/V&B *Equipment performance specifications*.

4.3.1 Locally manufactured equipment

It may seem desirable to use locally manufactured domestic refrigerators and freezers because they can be purchased with local currency and spare parts are freely available. However, tests have shown that domestic appliances are not generally suitable for vaccine storage, particularly in hot climates. WHO recommendations on this matter are as follows.

¹¹ The largest model currently available has a vaccine capacity of 85 litres but most models are much smaller.

-
- Locally manufactured refrigerators and freezers should only be used for bulk storage of vaccine if cold chain reviews show that the programme is well managed and that temperature monitoring procedures are reliable.
 - Standard domestic refrigerators should only be used for vaccine at the peripheral level, and then only if water bottles are used to improve temperature stability.¹² This is especially true in hot climates. Domestic refrigerators are unsuitable for vaccine storage because they are not designed to maintain the temperature range required and they warm up quickly when the electricity fails.
 - Domestic chest freezers should *not* be used to store vaccines but may be suitable for freezing ice packs.

4.3.2 Types of refrigerator and freezer

Both top-opening and front-opening models are available.

Top-opening models

Top-opening chest refrigerators and freezers are the first choice for bulk vaccine storage in places where cold rooms or freezer rooms are not justified. All the compression cycle refrigerators and freezers listed in the *Product information sheets* are of this type. Top-opening units have the following advantages over front-opening units.

- They are more efficient and often better insulated.
- The holdover time is greatly improved in the ice-lined refrigerator models that are available.
- No cold air is lost when the lid is opened.
- They are often less expensive.

However, top-opening units have the following disadvantages.

- Temperature stratification occurs in ice-lined refrigerators. Sub-zero temperatures may develop if the thermostat is not correctly adjusted. Better thermostats are now being fitted in an attempt to overcome this problem. Nevertheless, the presence of a large volume of ice in these units inevitably results in temperatures closer to zero than is ideal for the storage of freeze-sensitive vaccines, e.g. HepB.
- They occupy more floor space per litre of vaccine than front-opening models.
- Access to the vaccines is awkward. The vaccines must be packed systematically in order to ensure earliest-expiry-first-out (EEFO) handling.¹³

¹² See *How to modify a domestic refrigerator for safer vaccine storage*. Manila: WPRO; 1996.

¹³ EEFO handling is safer than first-in-first-out (FIFO) handling. In general, if two batches of vaccine are delivered at different times the one arriving second will have the later expiry date. However, this is not always the case, particularly if vaccines are obtained from different sources. The expiry date should always be checked and the vaccine with the shorter shelf-life should be distributed first, even if it arrived second.

Front-opening models

Small front-opening refrigerators or refrigerator/freezer combinations are best used at health facilities, where easy access to vaccine and a separate freezing compartment for ice packs are needed. Front-opening refrigerators and freezers have the following disadvantages for bulk vaccine storage.

- Most models are designed for domestic use and are poorly insulated.
- No ice-lined models are available.
- Cold air is lost every time the door is opened.
- Cold air leaks out if the door seals are defective.
- The shelves or drawers may limit the size of packages that can be stored.
- Vaccines can only be placed safely in the middle section because there is a temperature gradient in the cabinet.
- Vaccines may freeze if stored close to the evaporator plate. The tray below the evaporator must not be removed as this would further increase the risk of freezing.

Some of these disadvantages may be less significant in larger commercial models. However, no commercial models are known to comply with WHO standards.

Ice pack freezers

Special-purpose ice pack freezers have the highest freezing capacity and are the best choice if a large turnover of ice packs is expected. Both chest and front-opening models are available. An economical solution is to use a high-performance ice pack freezer for freezing the ice packs and to store them in a domestic chest freezer until they are needed.

WARNING: Ice packs should never be frozen in freezers containing bulk vaccine.

4.4 Refrigerants

Until recently the chlorofluorocarbon (CFC) gases R11 and R12 were very widely used as insulation foaming agents and refrigerants. However CFCs cause severe damage to the earth's ozone layer and contribute significantly to global warming. The Montreal Protocol¹⁴ called for the cessation of CFC consumption by 1 January 1996 in industrialized countries and by 1 January 2010 in developing countries. Hydrochlorofluorocarbon (HCFC) refrigerants, e.g. R22 and R502, are still allowed as transitional substances even though they also contribute, albeit to a lesser extent, to ozone depletion and global warming. HCFCs are to be phased out worldwide by 2040. Their use should be avoided wherever possible.

¹⁴ See: *Avoiding a double phase out: alternative technologies to HCFCs in refrigeration and air conditioning*. UNEP; 1999. This document includes tables of recognized refrigerants, with data on their global-warming and ozone-depleting potentials. For detailed information on issues relating to the Montreal Protocol, refer to the UNEP OzonAction programme on-line library at: <http://www.uneptie.org/ozonaction.html>

The hydrofluorocarbon (HFC) gas R134a is a common replacement for R12 in small refrigerators and freezers, as are hydrocarbons such as butane (R600) and isobutane (R600a). For safety reasons, WHO/V&B has decided not to recommend the use of flammable gases such as R600 and R600a in cold chain equipment.

Cold store manufacturers select refrigerants to suit the specified operating temperatures. R134a is often used for +4°C cold rooms but is not suitable for -20°C freezer rooms. Various alternative gases are available for this purpose, e.g. the blended gas R404a.

Some industrialized countries, notably the United Kingdom and the USA, continue to allow the export of equipment that uses R12, which is also being reclaimed and recycled in many countries, and simple tools are available for this purpose. Recycling should be encouraged where it is possible and applicable, because it ensures that equipment can continue to be used. Recycling also helps to reduce and delay the release of CFCs into the atmosphere. The skills and tools needed to handle several different refrigerants may not be available. Refrigerator technicians' tool kits, suitable for equipment containing CFC12, are listed in the WHO/UNICEF *Product information sheets*.

If possible, select refrigerators, freezers and cold rooms that use the same refrigerant. This has obvious operational advantages.

How to avoid contamination with incompatible refrigerants

- **Label equipment.** Fix a permanent label on the front of every appliance indicating the type of refrigerant it contains.
- **Label salvaged components.** Label every reusable component salvaged from old refrigeration circuits. The label must indicate the refrigerant used in the equipment from which the component was obtained. Salvaged components must only be used in equipment that uses the same refrigerant.
- **Provide the correct tools and spare parts.** Provide all service engineers with the correct tools and spare parts for the equipment for which they are responsible.

4.5 Calculating vaccine refrigeration capacity

Section 2 described a method for establishing storage volumes for individual vaccines. In the present section these data are used to calculate the total refrigeration capacity required to store all the vaccines in the schedule.

WARNING: Choosing the wrong grossing factor can lead to serious errors when ordering equipment. In order to avoid such errors, follow the recommendations set out below.

· **Refrigerators and freezers meeting WHO vaccine storage standards**

The WHO/UNICEF *Product Information Sheets* give the vaccine storage capacity of each model. Use the figure for vaccine storage capacity to calculate what equipment is needed. Do *not* use the figure for manufacturer's gross volume for this purpose.

· **Locally manufactured domestic refrigerators**

As noted above, WHO does not recommend the use of domestic refrigerators for vaccine storage at the primary and intermediate levels.

· **Cold stores**

The grossing factor for cold stores varies according to the size of the room and the layout of the shelving. Using the grossing factors given in Worksheet 2, calculate the approximate size of the room in order to check that the space allocated to house the cold store is large enough. The grossing factors given on the worksheet take into account that it is never possible to use 100% of the volume of a shelving unit. In each of the examples given it has been assumed that only two-thirds of the available shelf capacity can be used under normal circumstances.

Worksheet 2 uses the volumes calculated for the individual vaccines (Worksheet 1). Add up the volumes of all the vaccines to be kept at each of the two storage temperatures in order to obtain the total volumes. These totals are used to estimate what refrigeration equipment is required. An estimate of the total volume of diluents, droppers and transport boxes is also entered at the bottom of the worksheet. This figure can be used for planning storage at ambient temperature.

An Excel version of the worksheet is available on the CD supplied with this document.

Worksheet 2. Refrigeration capacity

Refrigerated storage

		As storage temperature		
		-15 to -25°C	+2 to +8°C	
A. Total vaccine volume (worksheet 1, row J):		<input type="text"/> litres	<input type="text"/> litres	A.
B. Total volume of other refrigerated items:		<input type="text"/> litres	<input type="text"/> litres	B.
C. Total volume of all items:	A+B	<input type="text"/> litres	<input type="text"/> litres	C.
Number of appliances required		Freezers	Refrigerators	
D. Manufacturer's net vaccine capacity:		<input type="text"/> litres	<input type="text"/> litres	D.
E. Number of units required: (round up result)	C/D	<input type="text"/> number	<input type="text"/> number	C.
Cold store size required		Freezer room	Cold room	
F. Cold room grossing factor: (see table below)		<input type="text"/>	<input type="text"/>	F.
G. Capacity required:	$(Cx F)/1000$	<input type="text"/> m ³	<input type="text"/> m ³	G.

Storage at ambient temperature

Storage for diluent and droppers			
H. Total diluent/dropper volume (worksheet 1, row J):		<input type="text"/> m ³	H
J. Volume of shelving units required:	H x 1.5	<input type="text"/> m ³	J.
Storage for transport boxes			
K. Total volume (worksheet 1, row L):		<input type="text"/> m ³	K.
L. Total room volume required for transport boxes:	K x 3	<input type="text"/>	L.

Notes:

- B) Other items include any non-EPI vaccines, sera and testing kits to be stored with EPI vaccines.
- D) Net vaccine capacities for WHO tested equipment are quoted in the *Product information sheets*. If other equipment is used, take the manufacturer's quoted gross storage volume in litres. For freezers, this number should then be divided by 1.5 to obtain an estimate for net vaccine capacity. For ice-lined refrigerators the numbers should be divided by 2.5.
- F) The cold store grossing factors shown in the table below are based upon the room layouts shown in Figure 6. The figures assume that only two thirds of the calculated net shelf volume can effectively be used for vaccine storage.

Room volume	5m ³	10m ³	15m ³	20m ³	30m ³	40m ³
Grossing factor	3.2	3.3	3.7	3.9	4.2	4.2

- J) Select shelf depth to suit diluent/dropper boxes (600mm typical). Select shelf spacing to suit boxes.
- K) Boxes assumed to be stacked on top of one another.
- L) Calculated volume allowing for circulation space.

4.6 Refrigerators or cold room? Freezers or freezer room?

Refrigerators and freezers are suitable for storing relatively small quantities of vaccine, i.e. up to about 1000 litres. Where larger quantities are kept, cold rooms and freezer rooms are more cost-effective.

The largest ice-lined vaccine refrigerator currently available stores 169 litres of vaccine. The largest vaccine freezers store 264 litres of vaccine. The practical upper limit to the number of such units in a vaccine store lies between 5 and 10.¹⁵

The smallest reach-in cold store models have a gross volume of about 2 to 3 cubic metres, although a gross volume of 5 cubic metres is probably the practical minimum with twin refrigeration units.

Before a cold room or freezer room can be installed the site has to be prepared to receive it. The unit then has to be assembled and commissioned. Two skilled workers take between one and four days to assemble and commission a cold store with a capacity of up to about 50 cubic metres. The cost of assembly is approximately 10% of the free on board (FOB) cost of the room and equipment.

4.7 Calculating capacity for ice pack freezing

Vaccines must be kept cold during transportation. They may be transported in vaccine carriers or in a refrigerated vehicle. Unless a refrigerated vehicle is used, all vaccine stores require ice pack freezers or a freezer room.

The required capacity for ice pack freezing depends on the chosen strategy for vaccine distribution. Let us suppose that distributions are made to four substores every four weeks. Deliveries could be spread evenly over the four weeks or they could all take place on the same day. In the second case the required ice pack freezing capacity would be four times greater than in the first. Despite this apparent disadvantage, concentrated delivery or collection may be the best option. For example, it may encourage the efficient use of transport. Vaccine distribution may also be planned to coincide with regular meetings with outlying EPI staff. Ice pack freezers do not have to be run permanently.

Use the following procedure to calculate the volume of ice packs needed.

- **Calculate volume of vaccine shipment**

Calculate the total volume of vaccine to be shipped to the substores for any one delivery. This determines the required total cold box volume.

- **Determine the minimum cold life required**

Consider the distance and time of the journey and the likely effect of disruption caused by weather conditions, bad roads or security alerts. This determines the required minimum cold life. Use the worst-case journey time for this purpose.

¹⁵ Multiple units impose large starting currents and generate much waste heat that has to be removed.

- **Select a suitable cold box**

Use the *Product Information Sheets* to select a suitable cold box or to check the performance of existing ones.

- **Calculate the number of cold boxes required**

Assess the number of substores to be served. This, together with the required volume (above), determines the required number of cold boxes.

- **Calculate the number of ice packs**

On the basis of the choice of cold box, calculate the number of ice packs required for each delivery.

- **Establish the required number of ice pack freezers**

Using Worksheet 3, calculate the required number of ice pack freezers. Ice packs can be frozen rapidly in special-purpose ice pack freezers and then stored in bulk in domestic chest freezers for subsequent use.

The capacity for freezing ice packs is reduced if the electricity supply is interrupted. No figures for this reduced performance are given in the *Product Information Sheets*. However, bulk ice pack freezers are unlikely to operate satisfactorily on less than 15-18 hours of electricity a day, particularly in hot climates. For 15-24 hours of electricity a day the freezing capacity is likely to be reduced roughly pro rata, depending on the efficiency of the appliance. For example, if electricity were available for only 20 hours a day the freezing capacity would be reduced to approximately 20/24 of the manufacturer's rated capacity.

An Excel version of the worksheet is available on the CD supplied with this document.

Worksheet 3. Ice pack freezing capacity

Store:			
<input style="width: 100%;" type="text"/>			
A. Total volume of vaccine delivered and/or collected per year:	<input style="width: 50px;" type="text"/>	litres	A.
B. Deliveries and/or collections per year:	<input style="width: 50px;" type="text"/>	number	B.
C. Average volume of delivery/collection:	A/B	<input style="width: 50px;" type="text"/>	litres C.
D. Vaccine capacity of cold box (see note 3):		<input style="width: 50px;" type="text"/>	number D.
E. Average number of cold boxes per delivery/collection: (round up result)	C/D	<input style="width: 50px;" type="text"/>	litres E.
F. Icepacks required per cold box (see note 3):		<input style="width: 50px;" type="text"/>	number F.
G. Weight of each icepack (see note 3):		<input style="width: 50px;" type="text"/>	kg G.
H. Maximum number of deliveries and/or collections per 24 hrs: (see note 5)		<input style="width: 50px;" type="text"/>	number H.
J. Max. weight of icepacks required per 24 hrs: (see notes 4 & 5)	E x F x G x H	<input style="width: 50px;" type="text"/>	kg J.
K. Selected equipment: <input style="width: 100%;" type="text"/>			
L. Icepack freezing capacity in kgs/24 hrs (see note 5):		<input style="width: 50px;" type="text"/>	kg L.
M. Number of icepack freezers required (round up):	J/L	<input style="width: 50px;" type="text"/>	number M.

Notes:

- 1) This worksheet is for estimating purposes only. It does not take account of situations where some vaccine deliveries are much larger than the calculated average volume.
- 2) If deliveries and/or collections are concentrated over short periods, the key requirement is to provide sufficient freezing and storage capacity to meet maximum demand.
- 3) Data for items D, F and G may be obtained from the *Product information sheets*, or from the vaccine carrier manufacturer.
- 4) Use the *Product information sheets* or manufacturer's data to select equipment. Equipment must be able to freeze and store the required weight of icepacks at the prevailing ambient temperature. If the electricity supply is intermittent, ask the freezer manufacturer to advise on how this will affect icepack freezing performance.
- 5) Icepack freezing capacity in the *Product information sheets* is generally quoted in kgs/24 hrs. The maximum weight of icepacks required in 24 hours largely determines the required icepack freezing capacity.

4.8 Installing refrigerators and freezers

Refrigerators and freezers must be installed correctly so as to ensure safety, reliability and maximum life.

1. **Ensure electrical safety.** All the wiring in a vaccine store should be carried out by a qualified electrician. All circuits should have effective earth protection. The power leads of appliances should be no longer than is necessary. If they are too long they should be cut back to the correct length. They must *never* be coiled in order to avoid obstruction, because coiled cables heat up and may catch fire.
2. **Ensure a stable electricity supply.** Provide a voltage stabilizer for each appliance in accordance with the recommendations in Section 8.
3. **Provide circuits with correct ratings.** Connect electric refrigerators and freezers to a power supply rated to take the maximum load of the appliances. The maximum electrical load occurs when a compressor starts up. Compressor start-up loads are five or six times the rated running loads. When power is restored after an extended supply failure, all the compressors in the vaccine store start simultaneously. Power circuits should therefore be rated to take the combined starting load of all the refrigerators and freezers connected to each circuit.¹⁶
4. **Wire units in permanently.** Refrigerators and freezers should be wired permanently into wall outlets. This overcomes the risk of deliberate or accidental disconnection. It is desirable to have a key-operated switch for each unit. Alternatively, the switches may be located in a lockable cupboard. If removable plugs are used they should be fixed to the wall outlets with adhesive tape. Wall switches should be taped permanently in the “on” position. If voltage regulators are used they should be ordered with wire-in connection units rather than with sockets.
5. **Avoid small, poorly ventilated rooms.** Refrigerators and freezers produce heat. When equipment is placed in a small room with poor ventilation this heat cannot escape and the equipment cannot operate effectively. In order to avoid overheating, provide a minimum of 4.5 m³ of room volume per 100 litres of vaccine stored. There should be some means of permanent ventilation in the room.
6. **Space units away from walls and other equipment.** It is essential to provide good ventilation around the equipment, particularly the condenser, which emits a lot of heat. Refrigerators and freezers should be spaced at least 20 cm away from walls and 30 cm away from other equipment.
7. **Mount units on pallets.** Refrigerators and freezers should be mounted about 10 cm clear of the floor on their own wooden shipping pallets, or on concrete or wooden blocks. This prevents corrosion when water is swept under units during floor cleaning. It also improves ventilation. Make sure that units are level and do not rock. Absorption cycle units must be perfectly level, otherwise they will not operate correctly.

¹⁶ In electrical engineering terms, there should be no allowance for diversity.

4.9 Prefabricated cold stores

4.9.1 Cold store enclosures

Cold stores are constructed with prefabricated modular insulated panels that are supplied in a range of standard length and widths, often in multiples of 300 mm. Panels are generally insulated with polyurethane foam in thicknesses ranging from 75 mm to 200 mm. Not all manufacturers offer panels over 100 mm thick, especially in the smaller room sizes. The wall and ceiling panels may be faced with plastic-coated zinc-plated or galvanized steel, or with aluminium or stainless steel. Floor panels generally have a patterned non-slip finish. Doors are insulated and fitted with airtight seals.

Most manufacturers can supply a full range of compatible components. These include shelving units, interior light fittings and flexible transparent plastic strip curtains for reducing cold air loss when the door is opened.

Safe working in cold rooms and freezer rooms

Cold rooms. Persons should not work for any length of time in a cold room unless they are wearing warm clothing.

Freezer rooms. Provide staff with proper protective clothing, including gloves. Never allow anybody who is not wearing this clothing to enter a freezer room. These precautions are particularly important in hot climates where staff wear thin clothes and may not appreciate the dangers of extreme cold.

4.9.2 Refrigeration units

Packaged refrigeration units have largely replaced units assembled on site. Site assembly relies on first-class workmanship, which, in practice, cannot be assured. The repair and maintenance of units assembled on site also requires skilled personnel. A defective packaged unit can quickly be replaced with a spare unit. Repairs to faulty components can then be carried out under controlled workshop conditions.

Self-contained monobloc refrigeration units are often used for cold stores of up to about 40-50 m³. These units may be wall-mounted or ceiling-mounted and are available with cooling capacities of up to about 20 kW. Ceiling-mounted units have the advantage of not taking up space that could otherwise be used for shelving units. This can be particularly helpful in smaller cold rooms.

Monobloc units only have to be connected to the electricity supply (single-phase or three-phase, depending on capacity) and to the temperature monitoring, alarm and control devices.

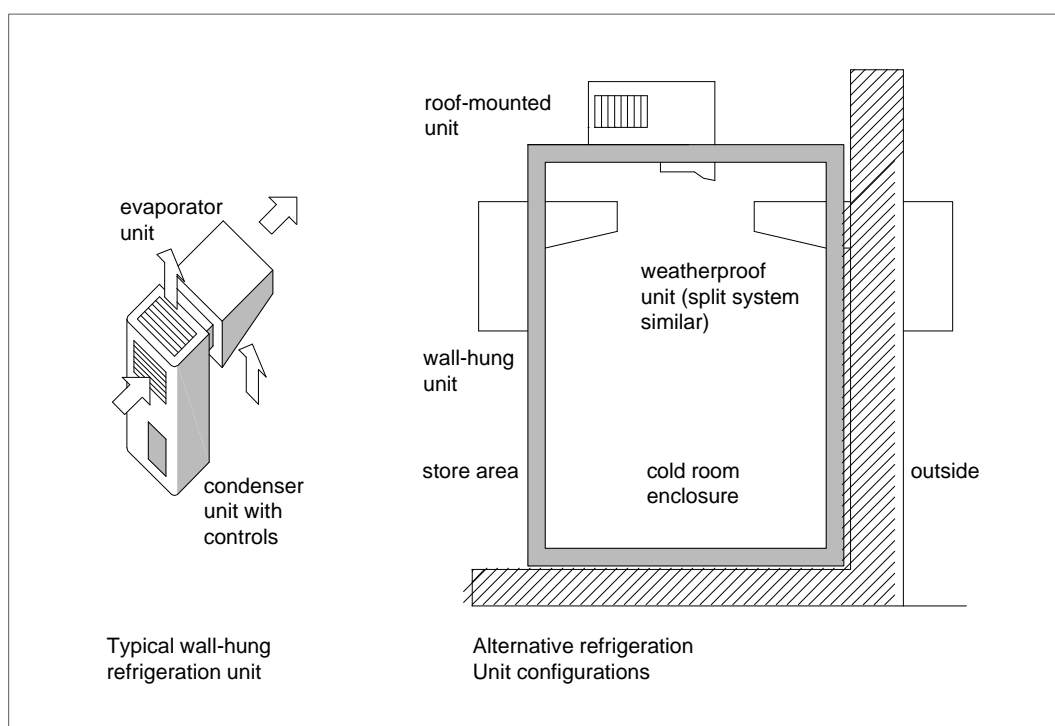
The condenser section generally discharges its waste heat into the space containing the cold store. This heat must be removed by natural or mechanical ventilation. Some monobloc units are designed so that the condenser discharges into the open air via an external wall (Figure 3).

Split-system refrigeration units with independent condenser and evaporator units are also available. These two components have to be connected on site. Split units have the advantage that the condenser unit can be located out-of-doors, thus avoiding the build-up of waste heat in the vaccine store, a particular problem in hot climates and with larger cold rooms.¹⁷

Figure 3 illustrates these alternatives.

All vaccine cold stores should have a 100% stand-by refrigeration capacity. In practice this means that rooms should be fitted with two identical refrigeration units operating on a duty-sharing basis with automatic change-over control.¹⁸ In this way both units can be maintained in a fully operational state.

Figure 3: Packaged refrigeration units



¹⁷ Because split systems require site-fabricated connections in the refrigeration lines they should only be specified where a high standard of installation and maintenance can be relied on.

¹⁸ For larger rooms in hot climates it may be necessary to have four units running in pairs.

Avoiding frozen vaccine in +2°C to +8°C cold rooms

In a +2°C to +8°C cold room the evaporator coil temperature is approximately -5°C and the temperature of the outlet air may be below 0°C. Consequently, freeze-sensitive vaccines may be destroyed if stored too close to the evaporator. In order to avoid this the following precautions should be taken.

- Refrigeration units should be sited so that no shelving lies within the plume of cold air close to the evaporator.
- Alternatively, the evaporator should be fitted with a mesh cage in order to prevent the storage of vaccine in the danger zone.
- A ceiling-mounted unit should always be in the centre of a circulation aisle so that vaccine stored on the upper shelves is not directly exposed to the stream of cold air coming from the evaporator.
- The air outlet from a ceiling-mounted evaporator should be directed away from any shelving in close proximity to it.

Refer also to Figure 6.

4.9.3 *Installation requirements and constraints*

1. **Floor loading.** Multi-dose vaccines are very heavy. It is essential that the floor structure of the building is adequate. In order to avoid structural problems it is desirable to locate cold stores on a concrete slab resting on the ground rather than on a raised floor. A safe working assumption is to allow for a floor loading of 700 kg/m² (about 7 kN/m²). A more accurate calculation may be necessary in situations where the floor loading is critical.
2. **Dimensional constraints.** Some manufacturers require a working clearance around the cold store in order to assemble the panels. Many manufacturers design their panels so that they can be assembled from the inside. This means that the amount of space required for the cold store is little more than the external dimensions of the enclosure itself. It is important to check this point with the manufacturer before finalizing the layout of the cold store accommodation. Wherever possible, leave a clear space all round the cold store for cleaning and inspection. Larger cold stores may require intermediate support beams for the ceiling panels. Clearances are also required around the refrigeration units. Wall-mounted units are usually located on the front wall of the cold store beside the entrance door. The projecting part of the unit is then accommodated in the working clearance at the front of the cold store. Roof-mounted refrigeration units project above the top of the store, and a clear working area between 0.5 and 1.5 metres above the roof of the store is required for maintenance purposes.
3. **Level floor.** The floor on which the cold store is erected must be level. A typical requirement is ± 3 mm. One way to create a level platform is to construct a timber framework to support the floor panels, shim it up until it is level and fill the voids between the framing members with dry sand. A raised plinth also stops water coming into contact with the cold store floor panels as a result of vigorous floor-washing. Long-term exposure to water can corrode the steel panel facings.

4. Low-temperature protection beneath cold rooms and freezer rooms.

A freezer room cools the ground beneath it. If the room is large enough the ground eventually freezes. Frozen ground expands and may lift and crack the concrete slab supporting the room. The risk is greatest with large freezer rooms in temperate and cold climates. Similarly, if a cold room or freezer room is located on an upper floor, the structure in contact with it cools down. This can cause surface condensation, especially in humid climates. Both problems can be overcome by laying an electrical resistance heater mat under the floor panels. The mat keeps the slab slightly warm and consequently the ground does not freeze and condensation does not occur. The cold room supplier should be asked to consider these issues at the tendering stage.

4.10 Transportable cold stores

Transportable cold stores are self-contained weatherproof units that do not need to be enclosed in a building. They are often based on a standard shipping container. They can be supplied with or without their own power supply.

A transportable cold store is more expensive to purchase and ship than a sectional cold store of the same capacity. However, the additional expense may be partly offset by a reduction in the costs of site preparation. A major advantage of transportable cold stores is that they can easily be moved to an alternative site when the need arises. This makes them particularly suitable for emergency use. In hot climates they should be shaded from the sun.

4.11 Site-built cold stores

In the past, cold store enclosures were commonly built on site with local materials. Cold store technology has now advanced and prefabricated enclosures are normally used. Site-built cold stores should only be contemplated in exceptional circumstances and only if the necessary skills are available. In some countries site-built cold stores may be less expensive to construct, especially if they are large. However, any initial saving is likely to be outweighed by higher maintenance and running costs.

The design of a cold store enclosure and the design or selection of matching refrigeration plant requires specialist engineering skills. The construction of a satisfactory site-built cold store demands high standards of construction and close attention to detail.

4.12 Temperature monitoring and alarm equipment

Every refrigerator, freezer and cold store used for vaccine storage must be fitted with an independent temperature-monitoring device. Ideally, an automatic alarm system should be available to alert staff whenever the temperature of the vaccine is outside the safe limits.

There must be reliable procedures for protection against failure at all times of day and night. Temperatures must be checked and recorded by a responsible member of staff. There must be a contingency plan to safeguard the vaccine if there is a long power cut or if the refrigeration equipment fails.

The following monitoring devices are suitable. Models are listed in the *Product information sheets*.

- Dial thermometer stored with vaccine.
- Integral dial thermometer built into equipment casing. An integral external thermometer is provided with any vaccine refrigerator or freezer that complies with WHO standards.
- Externally mounted temperature recording device (Section 4.12.1).
- Freeze indicator, monitoring once-only exposure to a temperature below 0°C.
- Temperature data logger, functioning as a reusable cold chain monitor. For example, it can be placed in a vaccine shipment at source and passed through the entire cold chain. At the end of the journey, time and temperature data can be downloaded to a personal computer and a complete picture of the vaccine's exposure to high and low temperature can be obtained.

Stem thermometers are also listed in the *Product information sheets*. However, experience has shown that users experience difficulty in reading these thermometers. For this reason they are best avoided.

Various combinations of these monitoring devices may be used.

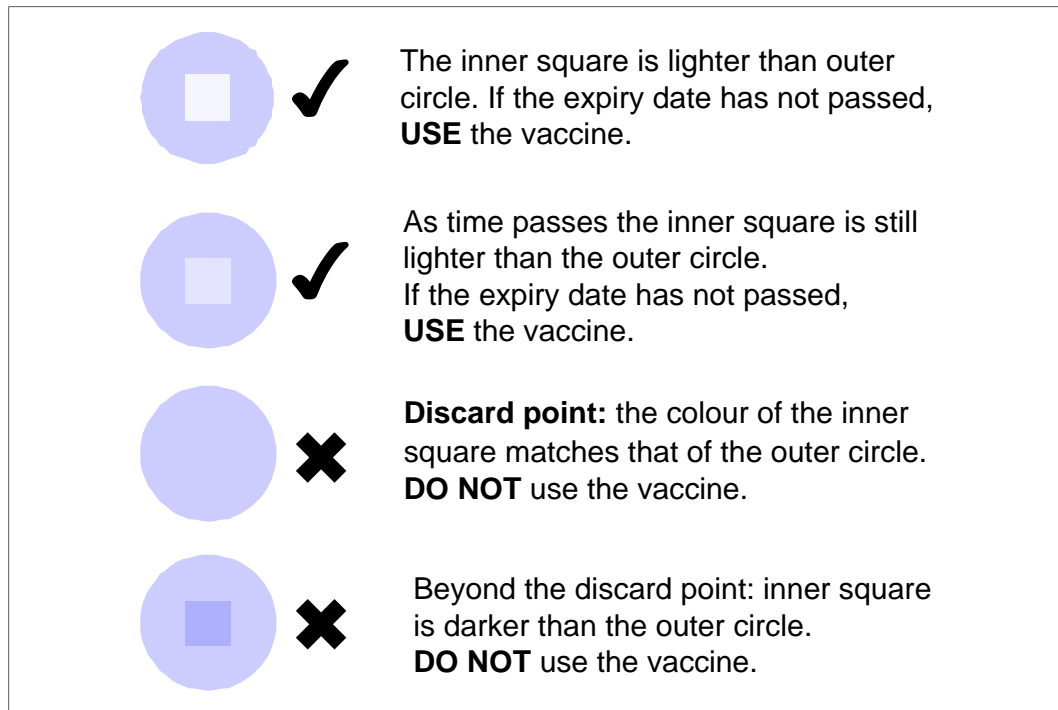
- In **freezers**: integral dial thermometer, dial thermometer.
- In **refrigerators**: integral dial thermometer, dial thermometer and freeze indicator.

Note that CCM cards continue to be listed in the *Product information sheets*. However, these cards are primarily intended for monitoring shipments from vaccine manufacturers to primary stores. They are difficult to use for in-country monitoring and their use for this purpose has been largely superseded by the introduction of electronic temperature data loggers.

Vaccine vial monitors (VVM) are the best time-temperature indicators in monitoring heat exposure to individual vaccine vials. During the period that vaccines remain in storage, the **expiry dates** of the stock must be regularly checked to ensure no older batches are present which should have been distributed before more recent arrivals. Also the **integrity of the stocks** should be checked by reviewing the status of the VVMs for each batch or lot. If either of these monitors shows any significant colour change during the period the vaccines have remained in storage, this indicates some weakness in the cold chain system, and repair or maintenance of the cold chain equipment may be needed.

Only vaccine stocks which are fit for use should be included in stock records. Any expired vials, heat damaged vials or vials with VVMs beyond the discard point should **not** appear in the available stock balance. If such vaccines need to be kept until accounting or auditing procedures have been completed for example, they should be recorded on a separate page or card until disposal.

Figure 4: How to read a VVM



4.12.1 Temperature monitoring in cold rooms and freezer rooms

Every cold room and freezer room should be equipped with an automatic recording device capable of continuous or intermittent temperature monitoring. The device should be fitted with alarm contacts.

Among the recorders available are the following.

- **Pen recorders.** Temperatures are recorded continuously on a circular paper disc or drum. Multi-channel recorders can record from more than one temperature sensor. Some are fitted with event recorders that monitor door-opening. The advantage of these devices is that charts can be kept as hard copies. Their disadvantage is that the charts and pens have to be replaced.
- **Digital recording systems.** These are electronic versions of mechanical recording devices. Multi-channel units can be programmed to monitor several cold stores, refrigerators or freezers. Some types allow data to be downloaded to a personal computer or printed out on a hand-held printer.
- **Computer-based data loggers.** These temperature sampling devices, based on personal computers, record temperatures at pre-programmed intervals.

Every cold store should have at least two temperature sensors. One should be fitted near the evaporator(s), close to floor level. The other should be near the door and high on the wall. Depending on the physical arrangement, rooms with twin refrigeration units may need another sensor near the second unit. Large cold stores may also need additional sensors in order to ensure that there are no cold spots or hot spots.

All devices should have mains-failure batteries with automatic recharge.

4.12.2 Temperature alarm systems

All cold stores must be fitted with temperature alarm systems. Multi-channel systems are available which can monitor several units simultaneously.

Refrigerators and freezers complying with WHO standards are not currently fitted with integral alarms or alarm contacts. Nevertheless, it is desirable that refrigerators and freezers in which bulk vaccine is stored be fitted with temperature alarm sensors linked to a multi-channel monitoring device.

Clearly, the alarm sounder must be located in a place where it can be heard. If the vaccine store is unattended outside working hours the best arrangement is to have the alarm system linked by telephone to the emergency services or to the duty officer's home.

Temperature monitoring checklist
Cold rooms and vaccine refrigerators:
<i>Temperature between +2°C and +8°C. Situation normal, no action necessary.</i>
<i>Temperature at or below 0°C. VACCINE AT RISK. Take immediate action to correct the low temperature and ensure that the problem does not arise again. Inspect the freeze-sensitive vaccines and/or carry out a shake test (see Annex 2) to establish if any has been frozen. Frozen vaccine must either be destroyed or tested to establish whether it is still potent. Make a report.</i>
<i>Temperature between +8°C and +10°C. No further action is necessary if there has been a temporary power failure. Check that the refrigeration unit is working, monitor the situation closely and take appropriate action if the temperature is not within the normal range at the time of the next inspection.</i>
<i>Temperature above +10°C. VACCINE AT RISK. Take immediate action to implement the agreed contingency plan and make a report.</i>
Freezer rooms and chest freezers:
<i>Temperature between -25°C and -15°C. Situation normal, no action necessary.</i>
<i>Temperature below -25°C. Adjust thermostat. Check that the temperature is within the normal range at the time of the next inspection.</i>
<i>Temperature above -15°C. No further action is necessary if there has been a temporary power failure. A temporary rise to +10°C is permissible following an extended power cut. Check that the refrigeration unit is working, monitor the situation closely and take appropriate action if conditions are not normal at the time of the next inspection.</i>
<i>Temperature above +10°C. VACCINE AT RISK. Take immediate action to implement the agreed contingency plan and</i>

4.13 Climatic factors

4.13.1 Temperature zones¹⁹

All refrigerators and freezers are classified on the basis of their performance in specific temperature zones:

- a hot zone that ranges from 0°C to +43°C
- a temperate zone that ranges from 0°C to +32°C
- a cold zone that ranges from -5°C to +32°C

The temperature zones for which the appliances were tested and approved, should be clearly marked on the appliance (see figure 5).

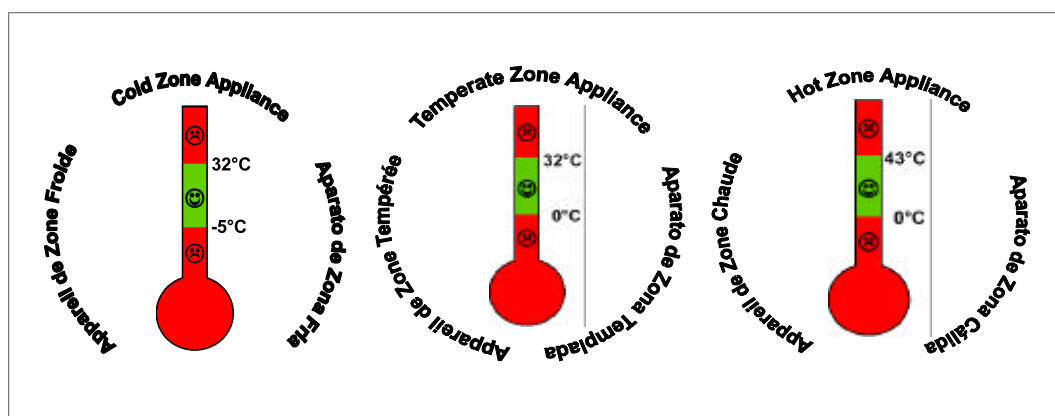


Figure 5: Temperature zones

The choice of temperature zones specific equipment can be based on one or a combination of the following considerations:

- A geographic distribution: use the equipment in geographic zones on the basis of the prevailing climate. The average temperature during the hottest/coldest months should be taken as criteria for the determination of the zones. Hot zone equipment can be used in temperate zones.
- A functional distribution: use temperate zone appliances in health facilities with sufficient ventilation or air conditioning, maintaining the temperature below +32°C and hot zone equipment at peripheral level where these conditions

¹⁹ For more detailed information on temperature zones please refer to Product Information Sheets, 2000 edition, WHO/V&B/00.13

are not met and temperatures regularly exceed 32°C.

4.13.2 Vaccine storage in hot climates

Refrigeration equipment generates much heat. Moreover, the efficiency of refrigeration equipment declines at high ambient temperatures. In hot climates, rooms housing refrigeration equipment must be kept as cool as possible. This can be achieved by active or passive means.

Rooms cooled by passive means should have ceilings that are at least 3 metres in height. Tall rooms allow hot air generated by occupants and machinery to rise well above the top of the refrigeration equipment. The hot air can then disperse through high-level openings.

- 1. Cooling by passive means in hot dry climates.** The walls of the vaccine store should be shaded from the sun. The store should have small high-level windows, preferably on opposite sides. A room on the lowest floor of a building with more than one storey is cooler than a room immediately below a roof. A building with thick walls stays cool during daytime for much longer than a building with thin walls. In hot dry climates the cool night-time air can be used to remove the heat of the day. This can be achieved by opening the windows in the evening or by drawing air through the space using an extract fan activated by a time switch.
- 2. Cooling by passive means in hot humid climates.** The walls of the vaccine store should be shaded from the sun. They should be perforated or should have large permanent openings on opposite sides at low level and high level. The openings should be at right angles to the prevailing wind so as to ensure maximum cross-ventilation. The roof space should be well ventilated. Planting around the building helps to cool the incoming air.
- 3. Cooling by mechanical means.** High ambient temperatures are more likely to develop if the vaccine store is small or if the refrigeration load is large. In buildings where internal temperatures regularly exceed +35°C it may be necessary to ventilate the space mechanically in order to remove heat that has built up. The hot air must be extracted from the room. Ceiling fans of the punka type are not suitable for this purpose because they may make matters worse by circulating heated air from the upper part of the room.

4.13.3 Vaccine storage in cold climates

In cold climates the temperature inside poorly or intermittently heated buildings where vaccine is stored can easily drop to near or below 0°C. In this event, vaccine stored in refrigerators and cold rooms is likely to freeze. HepB vaccine freezes and is destroyed at about -0.5°C. Toxoids, such as DTP and TT, freeze and are destroyed between -5°C and -10°C.

The two solutions to this problem are outlined below.

- 1. Permanently heat the vaccine store.** None of the vaccine refrigerators that currently meet WHO specifications offer any protection against ambient temperatures close to or below freezing. Work is being done to overcome this problem and the situation may change. Meanwhile, reliable seven-day-a-week

heating is essential in stores or health facilities where vaccines are kept in refrigerators.

- 2. Heat the cold room.** A cold room at +2°C to +8°C should be fitted with a heater circuit for frost protection unless the space housing the room is permanently heated and the heating system is 100% reliable.

4.13.4 Transporting vaccines in cold climates

Advice previously given by WHO and other agencies has generally concentrated on the need to keep vaccines cold during transportation in temperate and hot climates. Field experience in cold climates has shown that it is necessary to protect freeze-sensitive vaccines from exposure to ambient temperatures below 0°C. Observe the following guidelines if there is a risk of low temperatures during transportation.

- 1. Prepare warm packs.** Fill ordinary ice packs with cool tap water (+10°C is ideal). Do not freeze them.
- 2. Protect freeze-sensitive vaccines.** Keep DTP and its combinations with HepB and Hib, and DT, Td, TT, liquid Hib and HepB vaccines in the centre of the cold box or vaccine carrier and farthest from the warm packs.
- 3. Use a freeze indicator.** Place a freeze indicator and a thermometer in the cold box.
- 4. Check the warm packs.** Check the warm packs from time to time to ensure that they have not frozen. If they have started to freeze, thaw them out completely and replenish the water. Once warm packs are fully frozen the temperature inside the cold box drops rapidly in sub-zero conditions.
- 5. Use a heated vehicle.** Where possible, use a vehicle with a heated goods compartment that maintains the internal temperature above 0°C. Never leave cold boxes or vaccine carriers in unheated vehicles, especially overnight. If the programme uses a refrigerated vehicle for vaccine transportation, ensure that it is fitted with a low-temperature heater circuit in order to provide protection for the vaccine during the winter months.
- 6. Avoid cold conditions.** Do not leave cold boxes or vaccine carriers outdoors or in unheated rooms.

4.14 Lighting

BCG, measles, rubella, MR and MMR vaccines are damaged by exposure to daylight and fluorescent lighting. These vaccines are normally supplied in vials made from dark brown glass, which gives some protection against light damage. Nevertheless, the vials should be kept covered and protected from light at all times. Vaccine packing areas should be artificially lit if possible. It is desirable to use conventional incandescent light bulbs in cold stores, vaccine packing areas and other places where vials are likely to be removed from their packaging.

5. Space planning

5.1 Planning vaccine stores

Space is required in a vaccine store for a vehicle loading bay, a room to accommodate the refrigeration equipment, a room to store diluents, droppers, packing materials and other consumables such as injection equipment, waste management supplies and spare parts, a room to pack the vaccine for dispatch, and an office for the storekeeping staff. If possible the different activities should be housed in the same building, although bulky consumables such as injection equipment and spare parts may have to be stored elsewhere.

5.2 Vehicle loading bay

The detailed design of a vehicle loading bay is governed by the size and type of vehicle used. The following matters should be considered.

1. **Access.** The loading bay and the route to it must be planned to allow easy access for the largest vehicle used.
2. **Security.** Some vaccines, such as HepB, have a black market value. The loading bay area should therefore be visible from the storekeeper's office. Security is a particular problem if the vaccine store is located in a medical stores compound where other valuable commodities are kept.
3. **Weather protection.** A loading bay should preferably have a projecting canopy to protect workers, vehicles and vaccines from sunlight, rain or snow during loading and unloading.
4. **Loading dock.** Delivery vans can be loaded from ground level. However, it is more convenient to load and unload lorries from a loading dock at the same level as the floor of the vehicle. This makes it possible to use a trolley to wheel vaccine into the vehicle. Alternatively, the lorry may be fitted with a tail lift. A raised loading dock should be between 1.2 and 1.4 metres above the vehicle parking area. Ideally, it should be built to match the height of the delivery vehicle or should be fitted with a dock-levelling device.
5. **Special requirements for refrigerated vehicles.** Some programmes use refrigerated vehicles to distribute vaccine from the primary store. Specialized facilities and training are necessary if such vehicles are to be operated safely and effectively. A refrigerated vehicle must be fitted with a temperature logger; there should be a weatherproof electrical outlet to power the vehicle's refrigeration unit during loading and unloading operations; and there should be sufficient space to store delivery crates if these are used in place of cold boxes.

More general guidance on the management of medical stores is given in Chapter 23 of *Managing drug supply*.

5.3 Refrigeration equipment area

The refrigeration equipment area should be laid out so that diluents and OPV droppers can be stored on easily accessible shelves close to the cold store. Each vaccine manufacturer supplies diluent that is only compatible with its own vaccine. It is very important that diluents be systematically stored and subjected to the same rigorous stock control procedures as the vaccines with which they are intended to be used. Experience shows that good control of diluent stock is more likely to be achieved when it is stored close to the vaccine with which it is to be used.

The information in this section assumes that prefabricated cold stores with twin-packaged refrigeration units are in use. Figure 6 shows typical layouts and clearances for cold stores in a range of sizes from 5 m³ to 40 m³. Figure 7 shows the layout and clearances required around refrigerators and freezers.

The design of cold stores exceeding about 50 m³ is outside the scope of this guideline. Specialist controls are needed so as to ensure that even temperatures are maintained throughout. One way of avoiding this complexity is to install several smaller cold stores with shared dividing walls.

The internal height of vaccine cold stores where stock is moved by hand should not exceed 2.3 metres. This limit ensures that vaccine on the top shelves is accessible without the use of steps. Rooms should be planned so that they accommodate the greatest possible length of shelving, taking account of the locations of the entrance door and the refrigeration units. A square plan is not necessarily the most space-efficient, especially in smaller units. The optimum locations of refrigeration units and shelving largely determines the layout.

Stock should be arranged so that there is free movement of air between the vaccine packages, which should be stored about 5 cm away from the walls of the room. This allows air movement behind the stock and helps to ensure an even temperature. Slatted shelving also assists air circulation and is therefore preferable to solid shelving.

5.4 Vaccine packing area

Figure 8 is a schematic layout for a typical vaccine packing area. The size of the space required depends on the maximum daily throughput and the number of staff employed. The packing area should connect to a direct route between the vaccine store and the vehicle loading area. It must not form part of a main circulation route because it has to be kept cool and secure. Vaccine packing involves a number of linked activities, all of which should be accommodated in the same space.

Figure 6: Cold store planning and dimensions

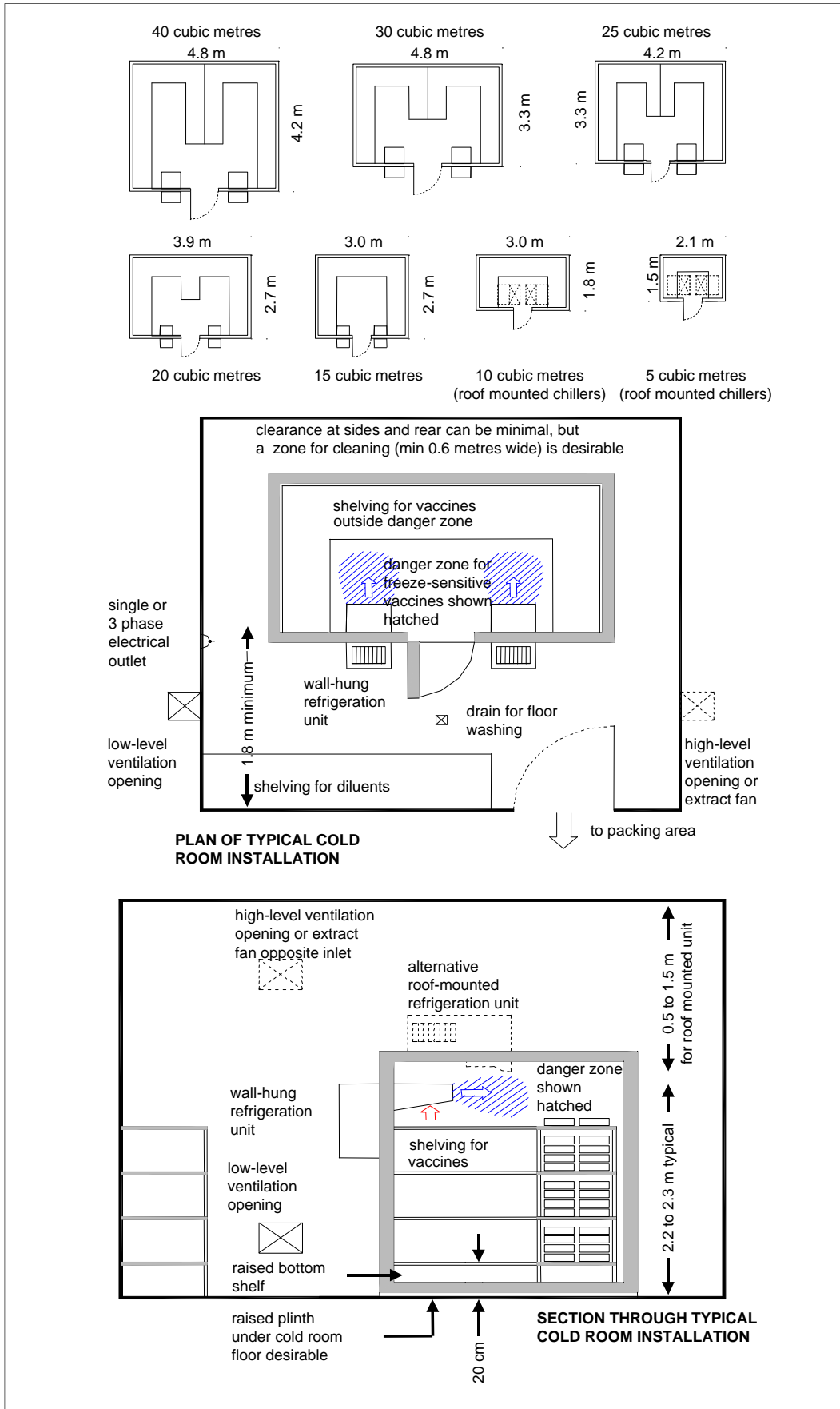
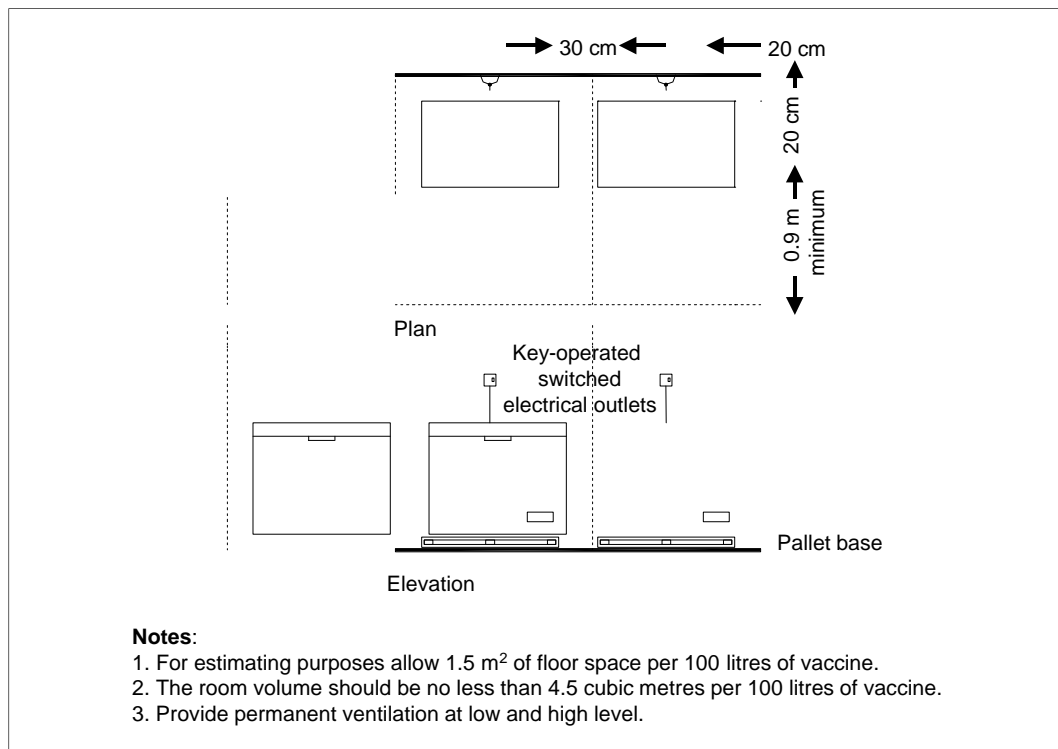


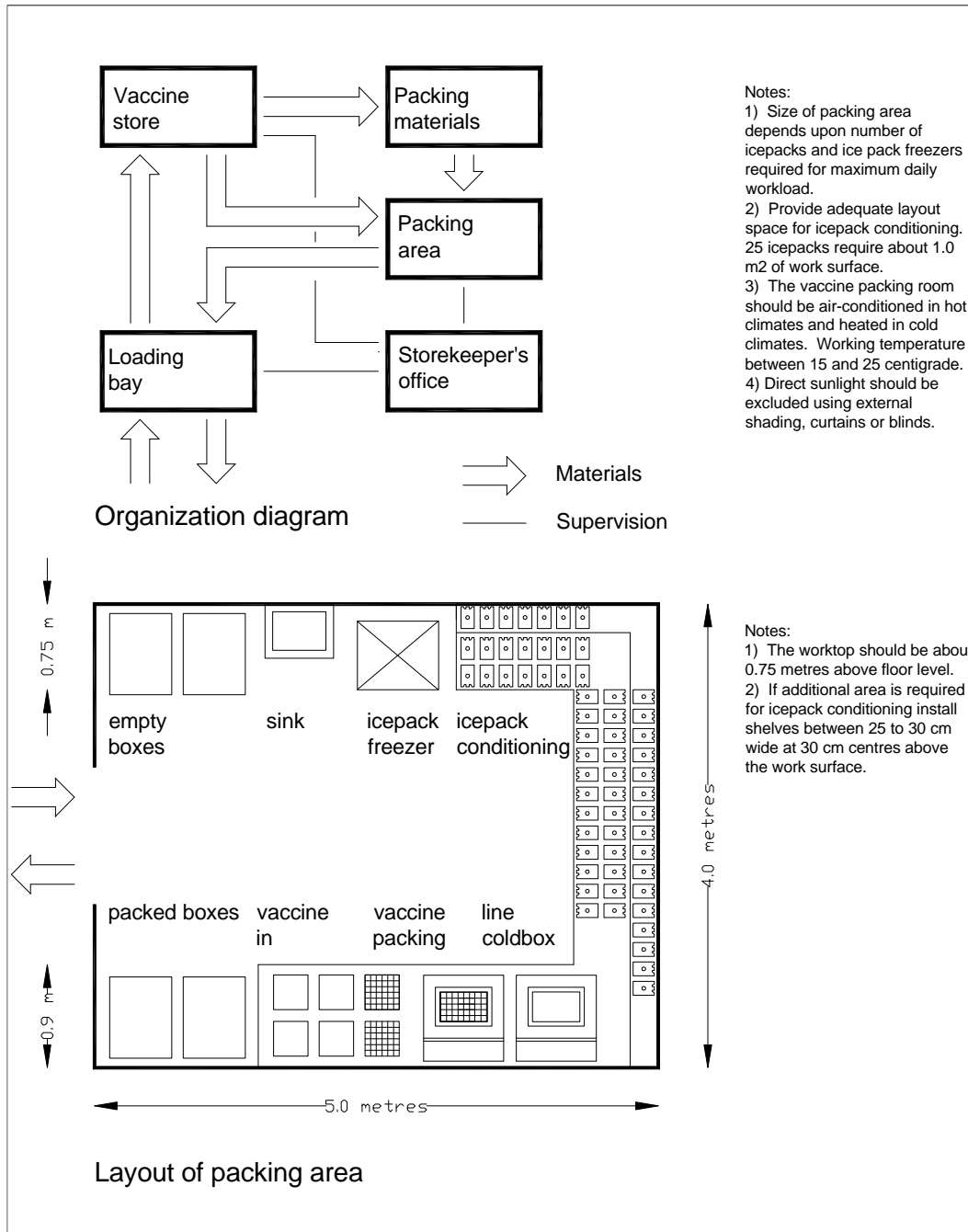
Figure 7: Refrigerator and freezer layout



- **Activity 1:** A written delivery order is received from the storekeeper.
- **Activity 2:** The correct number of ice packs is removed from the ice pack freezer and laid out in a single layer on the work surface until they are conditioned.
- **Activity 3:** The correct quantities of vaccine and diluent are brought from the vaccine store and placed on the work surface. A check is made to ensure that the diluent matches the vaccine.
- **Activity 4:** The order for each destination is assembled and checked and the delivery notes are completed.
- **Activity 5:** The insulated transport boxes are lined with conditioned ice packs.
- **Activity 6:** Vaccine is packed in the transport boxes and these are sealed and stacked so that they are ready for loading on to the delivery vehicle.
- **Activity 7:** The transport boxes are loaded on to the vehicle.

Clearly, activities 2 and 5 are not applicable if refrigerated transport is used.

Figure 8: Vaccine packing area



The packing area should be laid out so as to encourage a logical flow of work. Vaccines should be moved as little as possible in order to minimize the risk of breakage. There should be a sink in the packing area for hand-washing and provision for hygienic hand-drying.

Conditioning ice packs

Ice packs come out of the freezer at a temperature of about -20°C . They must be kept at room temperature for a period in order to allow the temperature of the ice at the core of each one to rise to 0°C . This process is called "conditioning". The standard advice has been that an ice pack is adequately conditioned as soon as beads of water cover its surface. Experiments have shown that this is not always so and that cold-sensitive vaccines, particularly HepB, can freeze inside a cold box even when ice packs appear to have been correctly conditioned.

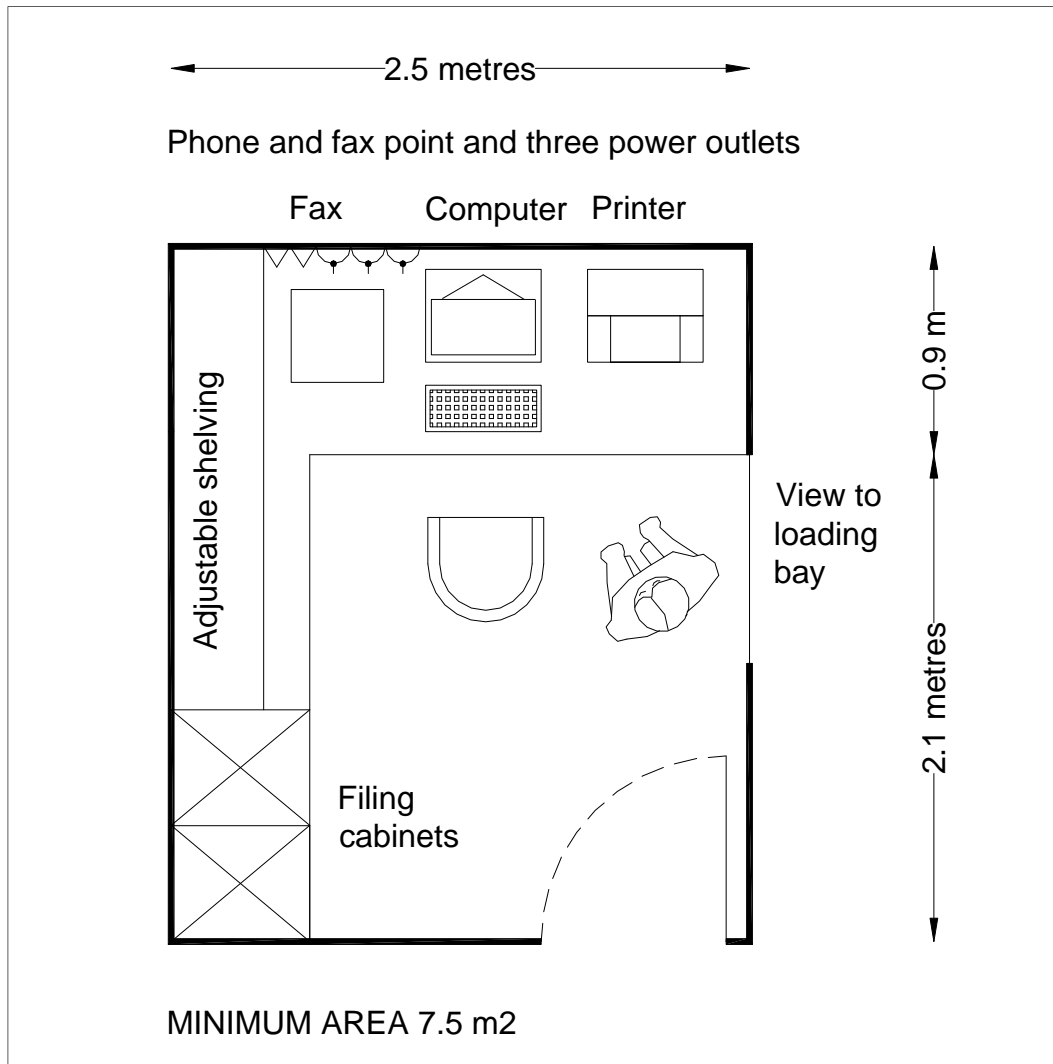
When ice packs are laid out on a table they create their own microclimate. This extends the conditioning process. The following procedure is recommended.

- Lay out ice packs, preferably in single rows but never in more than two rows.
- Leave a 5 cm space all round each ice pack.
- Wait until there is a small amount of water inside the ice packs. This takes up to an hour at $+20^{\circ}\text{C}$ and rather less at higher temperatures. Shake one of the ice packs every few minutes. The ice is conditioned as soon as it begins to move about slightly inside its container.

5.5 Storekeeper's office

Figure 9 shows the layout of the vaccine storekeeper's office, which should be located as close as possible to the vaccine store, the packing area and the loading bay. This helps the storekeeper to supervise activities. There should be adequate space and connections for a telephone, a fax machine and a computer terminal. Even if these are not installed immediately it is likely that they will be required in the future.

Figure 9: Storekeeper's office



5.6 Packing materials store

Transport boxes, cold boxes and other packing materials should be stored near the vaccine packing area.

The volume of the transport boxes received with each international vaccine shipment can be calculated using Worksheets 1 and 2. If these boxes are to be used for onward shipment to intermediate stores the packing materials store must clearly be large enough to hold them.

At the intermediate level the original transport boxes are likely to be discarded or used for other purposes. Vaccine carriers are used thereafter for delivery to health facilities. At the intermediate level one or other of the following circumstances may occur.

- 1. The intermediate store or the health facility collects vaccine.** In this case the store supplying the vaccine provides frozen ice packs. The collecting store brings its own vaccine carrier and returns a set of melted ice packs for the next collection.

2. **The intermediate store or health facility receives vaccine.** In this case the store supplying the vaccine provides both the vaccine carrier and the frozen ice packs. The vaccine is delivered and the empty vaccine carrier and the melted ice packs are returned to base. These have to be stored until the next delivery is made.

Vaccine carrier volumes are given in the *Product information sheets*.

5.7 Store for injection equipment and waste management supplies

In order to achieve the goals set out in the WHO-UNICEF-UNFPA safe injections policy,²⁰ adequate space must be allocated for storing AD syringes and matching waste management supplies. These products should be fully integrated into the vaccine supply chain as part of the proposed bundling policy, the intention of which is to ensure that for every dose of vaccine there is always a sterile syringe and that for every used syringe there is always a safety box in which it can be safely discarded.

Storage requirements for AD syringes and safety boxes are estimated as indicated below.

- **AD syringes.** Allow about 1 cubic metre of net storage volume for every 15 000 syringes or 0.067 cubic metres per 1000 syringes. These are worst-case figures. The requirement for the syringes in the 2000 edition of the *Product information sheets* ranges from 16 000 to 29 000 units per cubic metre.
- **Flat-packed safety boxes.** There is considerable variation in the packed volume of safety boxes before they are assembled and in the number of syringes each type can accommodate. Table 3 is based on data from the 2000 edition of the *Product information sheets*, normalized to show the potential syringe storage capacity per cubic metre of packed boxes and the packed volume of the boxes for every thousand 0.5-ml syringes.

Table 3: Storage of flat-packed safety boxes

PIS 2000 reference	Capacity (litres)	Capacity (syringes)	Syringe capacity per m ³ of packed boxes	Volume of packed boxes per 1000 syringes (m ³)
E12/01	5	140	159 091	0.006
E12/02	5	155	193 750	0.005
E12/03	5	117	72 401	0.014
E12/04	5	110	137 500	0.007
E12/07	5	138	74 693	0.013
E12/08	10	326	244 500	0.004
E12/09	20	654	228 900	0.004

²⁰ *Safety of injections: WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunization services* (WHO/V&B/99.25).

- **Assembled safety boxes.** Once safety boxes have been assembled and used they must be stored in preparation for safe disposal. In general, safe disposal takes place at health facilities and the amount of storage space required is not great. However, some countries may choose to collect filled boxes in order to dispose of them in a high-temperature incinerator at a central location. Transportation and storage volumes then become logistically significant. Table 4 gives the data for assembled boxes in the same format as that of Table 3.

Table 4: Storage of assembled safety boxes

PIS 2000 reference	Capacity (litres)	Capacity (syringes)	Syringe capacity per m ³ of assembled boxes	Volume of assembled boxes per 1000 syringes (m ³)
E12/01	5	140	23 840	0.042
E12/02	5	155	26 147	0.038
E12/03	5	117	18 490	0.054
E12/04	5	110	19 298	0.052
E12/07	5	138	18 948	0.053
E12/08	10	326	29 084	0.034
E12/09	20	654	29 358	0.034

5.8 Spare parts store

The space needed for spare parts storage depends entirely on the arrangements for servicing the cold chain equipment. If servicing is carried out by health ministry technicians it may be necessary to keep spare parts and tools in the vaccine store. If, however, a private company or another government agency is responsible for servicing, most spare parts are likely to be stored elsewhere. This issue should be considered at the planning stage.

5.9 Heating and air-conditioning

In cold climates all working areas, including the vaccine packing area, must be heated. In hot climates the vaccine packing area must be air-conditioned. It is also desirable that the storekeeper's office be air-conditioned. The temperature of the vaccine packing area should be kept between +15°C and +20°C. It should never exceed +25°C. Refer to Section 4.10.

6. Choosing a site

The checklist below outlines the main steps in the process of site selection.

- 1. Determine the size of the store and its access requirements.** Using the information set out above, calculate the floor area required for the vaccine store and the size of delivery vehicles.
- 2. Review potential sites.** Consider the following alternatives.
 - a) Space in a government warehouse or other government building that can be adapted for the purpose.
 - b) Commercial warehouses that can be purchased or rented.
 - c) Empty sites that can be developed.
- 3. Assess natural hazards.** Consider the following.
 - a) Are any of the potential sites at particular risk from natural hazards, e.g. tidal surges, storms or earthquakes?
 - b) What precautions can be taken to guard against these risks?
 - c) If any of the preferred sites were to be severely damaged, how would this affect the routine immunization programme and a post-disaster emergency response?
- 4. Compare the suitability of possible sites.** Consider the following issues before a site is finally selected
 - Access**
 - a) Is the site close to the relevant transport links, including roads and airport?
 - b) Is the site well served by public transport? Public transport is needed by store staff. It may also be required by health workers when collecting vaccine.
 - c) Is the site conveniently located for permanent and supervisory staff?
 - d) Is the route to the site accessible throughout the year?
 - e) Is there adequate access and parking space for vehicles?
 - Services**
 - a) Does the site have a reliable mains electricity supply?
 - b) Is there a stand-by generator?
 - c) Does the site have a reliable telephone service?

Security

- a) Would the site be secure?
- b) Could the store be properly monitored and supervised outside normal working hours?

Site development

- a) Is the site well drained and without any risk of flooding?
- b) Are ground conditions suitable for building economically?
- c) Could the site be developed at an acceptable cost?

Future conditions

- a) Would access to the site and the security of the electricity and communications systems be adversely affected by future development in the area?

7. Building standards

Vaccine stores should be housed in permanent buildings, which should be designed and constructed to a good standard that is appropriate for local climatic conditions. Temporary buildings should be avoided. They are rarely satisfactory and are expensive to maintain. If funds are scarce there is a tendency to continue using temporary buildings indefinitely. If temporary buildings are all that is available the use of transportable cold stores may be justified.

If the store is in an area affected by flooding it should be on high ground or raised above flood level. The loss of a major vaccine store in a natural disaster has potentially life-threatening consequences for the population concerned.

If an existing building is used it must be in good condition. If necessary it should be repaired and upgraded.

The following minimum standards are desirable in any vaccine storage building. Most are essential in a primary or intermediate store.

Roof and ceilings

- In good condition, completely free from leaks.
- Roof space insulated and/or ventilated in hot climates and insulated in cold climates.
- Ceiling in good condition and freshly painted. The ceiling should completely seal off the roof space in order to protect against dust and pests.

Walls and columns

- In good condition, free of cracks and other structural defects.
- Free from rising or penetrating damp.
- Insulated in cold climates.
- Finished internally and externally to a good standard. The internal finishes should be dust-free.

Windows, screens and doors

- Windows should be in good condition, with no broken glass, and should have secure locks or catches.
- All window openings should be fitted with security grilles.
- All external doors and all internal doors to rooms containing valuable items should be fitted with security locks.

Floors

- Smooth, level and completely free from rising damp.
- Finished with floor paint, tiles, terrazzo, vinyl sheet or some other washable dust-free surface.
- Floors on which cold stores are to be built must be levelled to a tolerance of ± 3 mm over the area of the cold store.
- It is desirable for cold stores to be raised on a low plinth (25-50 mm). This prevents water used for floor washing from running under the floor panels. Alternatively, the junction between the cold store and the floor may be sealed with waterproof mastic.

Fire protection

- The building should be easily accessible to the fire service. A water hydrant should be provided if this is required by the fire service.
- The building should not contain a kitchen or other significant fire hazard.
- The building should be of non-combustible construction or should be lined with non-combustible sheet materials.
- Rooms used for storing packing materials and other combustible items should be isolated from the vaccine store by fire-resisting construction and by fire-resisting self-closing doors.
- Flammable rubbish, such as cartons and boxes, must not be allowed to accumulate in the store.
- Smoking should be forbidden and “No Smoking” signs should be displayed throughout the store.
- The building should be fitted with fire and smoke detectors connected to an external alarm sounder. If possible the alarm system should have an automatic telephone connection to the fire service.
- There should be at least one carbon dioxide or powder fire extinguisher close to the entrance door for extinguishing electrical fires.
- In addition there should be at least two carbon dioxide, powder or water extinguishers within 30 metres of any part of the vaccine store for extinguishing other types of fire.²¹
- Fire-detection and fire-fighting equipment must be inspected regularly, and staff must receive adequate training in fire-fighting techniques and emergency action. There should be regular fire drills.

²¹ In general the number, size and type of extinguishers should conform with local fire authority requirements. These recommendations are based on British Standard 5306, Part III: *Code of practice for selection and installation of portable fire extinguishers*.

Electrical services

- All power and lighting circuits must be in a safe condition, tested and approved to national standards by a qualified engineer or electrician.
- Power circuits serving refrigeration equipment must be rated to suit the required refrigeration starting and running loads.
- Ancillary electrical equipment (fans, air-conditioners, light fittings, etc.) should have no significant electrical or mechanical defects.

Heating and water supply systems

- All pipework should be in good condition, free of leaks.
- Heating systems should be fully operational and controllable.

Drainage

- Drainage systems should be fully operational and free of blockages.
- The surface water drainage system to the building and site must be effective even at the height of the rainy season.

Pest control

- The building should be designed and maintained so as to minimize infestation by insects, rodents, bats or other pests.

Cleaning

- The building should be cleaned two or three times a week and adequate equipment should be available for this purpose.

Security

- The building should be secured against break-ins and should be located so that access to it is controlled.

8. Power supply

8.1 Reliability

The reliability of the electricity supply is a key issue when refrigeration equipment is being chosen. Where power cuts exceed 8 hours in 24 hours the use of ice-lined refrigerators and high-performance freezers is essential (Section 4). Ice-lined refrigerators are available with holdover times of up to 32.5 hours at an ambient temperature of 43°C. Vaccine freezers can achieve a holdover time of up to 17.5 hours at this ambient temperature.

8.2 Stand-by generators

If extended mains failures occur, vaccine is destroyed unless there is an alternative source of power. It is essential to assess the risk of such failures, which may arise for many reasons. Predictable failures can be planned for. They generally arise when the power supply network is overloaded at times of peak demand or when electricity is only made available for a limited number of hours per day. Less predictable failures arise as a result of mechanical breakdown, a lack of fuel or seasonal storms.

All sites storing large quantities of vaccine should have a stand-by power supply. Often this is achieved most economically by locating the vaccine store in a hospital compound or on some other site that already has a stand-by generator. If possible, however, the generator should serve the vaccine store alone.

Replacing large quantities of damaged vaccine is expensive and extremely disruptive. It may not be possible to replace vaccines quickly in a particular country because world stocks are limited. Moreover, emergency replacement from a finite world stock disrupts the supply of vaccine to other countries.

8.2.1 Generator sizing and selection

The *Product information sheets* give advice on choosing and buying a generator and provide an outline specification. The size of the generator should be calculated by a qualified electrical engineer or the equipment supplier.

8.2.2 Generator control and operation

A generator that serves only a vaccine store should be fitted with an automatic starting device linked to the alarm system of the cold store or refrigerator/freezer. If the vaccine store is served by a compound generator, this is generally started by an automatic mains failure device. In this case there is no requirement for an alarm-triggered start-up.

All generators should be run at least once a week and should be serviced regularly so that they remain operational. The fuel tank should be kept full.

8.2.3 Generator location, security and fire protection

A generator should be sited so that it does not create a fire hazard. Typically, it should be located in a separate building or in a weatherproof enclosure. The fuel tank should be isolated and should be surrounded by a low wall or an earth bank in order to prevent fuel spills from spreading. Both the generator and the fuel tank should be located in a secure compound for the prevention of theft. The fuel filler cap should be locked and the fuel line should be protected so that it cannot be tampered with. Fire extinguishers capable of extinguishing fuel oil, engine and electrical fires should be installed close to the generator and fuel tank.

8.2.4 Fuel supply

The fuel supply for the generator must be a priority allocation. A running log should be kept in order to monitor fuel consumption.

8.3 Voltage stability

In many countries there are severe voltage fluctuations in the mains power supply. Most compressor motors are damaged by fluctuations exceeding about $\pm 15\%$. The problem can be overcome by fitting each piece of refrigeration equipment with a voltage stabilizer.

Voltage stabilizers for cold stores should be specified by the cold store supplier. When a voltage stabilizer is ordered for a refrigerator or freezer the following information should be given to the supplier:

- Actual voltage fluctuations (recorded by an engineer or electrician).
- Nominal voltage.
- Whether a single-phase or three-phase supply is present.
- Frequency (50 Hz or 60 Hz).
- Nominal power of appliance compressor in watts.

The nominal power rating of the stabilizer should be about five times the nominal power of the compressor in order to allow for the starting load.

9. Procurement, commissioning and maintenance of equipment

9.1 Procurement

The procurement of cold chain equipment, especially cold stores, is not simply a question of preparing and inviting tenders. The person responsible for procurement must ensure that the following steps are taken.

- **For cold rooms and freezer rooms.** Prepare a short list of manufacturers and installers. If local tendering procedures permit, contact suitable cold store manufacturers/installers and obtain technical information and budget costs. Otherwise, obtain this information through a formal prequalification tendering procedure. Technical information received should be used in conjunction with *Equipment performance specifications and test procedures. E1: Cold rooms and freezer rooms* (WHO/V&B/02.34) in order to prepare tender specifications.
- **For refrigerators and freezers.** If possible, select equipment from the current edition of the *Product information sheets*.
- **Specify preparation of buildings.** Draw up specifications to ensure that the buildings are correctly prepared to receive the cold chain equipment, with adequate power outlets, etc.
- **Prepare buildings.** Arrange building contracts to prepare buildings and monitor progress and standards.
- **Arrange storage space.** Unless the cold chain equipment is to be delivered directly to the point of use, arrange temporary storage space for it.
- **Prepare tender specifications for equipment and for service agreements.** Prepare comprehensive specifications that clearly define performance requirements, delivery arrangements, spare parts requirements, payment terms and warranty terms. If appropriate, specify arrangements for installation and after-sales service.
- **Obtain tenders.** Obtain tenders in accordance with local tendering procedures.
- **Enter into contract with the supplier/installer.** Finalize a detailed delivery and installation programme with the successful tenderer and sign the contract.
- **Monitor delivery and installation of cold chain equipment.** Ensure that the equipment is delivered in good condition and that the installation is correctly carried out.
- **Commission equipment.** Ensure that the equipment is tested and that it meets the specified performance standards.

- **Monitor equipment performance during warranty period.** Receive reports of equipment breakdowns and ensure that equipment repair or replacement is carried out.
- **Monitor service agreements.** Monitor the performance of service agents and ensure that service agreements are complied with.

Table 5 gives an example of a programme for the procurement of cold chain equipment.

Table 5: Example of a cold chain equipment procurement programme

Programme item	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1.Prepare cold chain equipment tender documents	■	■										
2.Specify preparatory work to buildings	■	■										
3.Prepare buildings			■	■	■							
4.Obtain tenders for cold chain equipment			■	■	■							
5.Place order for cold chain equipment					■	■						
6.Approve building preparation					■	■						
7.Lead time for delivery of cold chain equipment					■	■	■					
8.Deliver and install cold chain equipment							■	■				
9.Commission equipment								■	■			
10.Train staff								■	■	■		
11.Monitor equipment performance								■	■	■	■	■
12.Monitor service agreements								■	■	■	■	■

9.2 Tender specifications

The WHO document *Equipment performance specifications and test procedures E1: Cold rooms and freezer rooms* (WHO/V&B/02.34, revision date: 15 November 2002) may be used as a basis for specifying cold stores. The latest version of the *Product information sheets* may be used as a basis for selecting other cold chain equipment.

Tender specifications must clearly describe the responsibilities of the contracting parties, as illustrated below.

1. **Supply-only tenders.** In a supply-only tender (e.g. the supply of refrigerators or freezers), be clear about the critical point of delivery. For example, is the supplier responsible for delivery to the port of entry (cost, insurance and freight [CIF]) or for delivery with duty unpaid or duty paid (DDU or DDP)²² to a distribution point within the country concerned or to individual vaccine stores?

²² For an explanation of common trade terms refer to Management Sciences for Health, *Managing drug supply*, Chapter 17, Fig. 17.2; Kumarian Press; 1997. Or refer to International Chamber of Commerce, Incoterms 2000 at <http://www.iccwbo.org/incoterms/preambles.asp>

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2. **Supply-and-install tenders.** Cold stores are generally tendered on a supply-and-install basis. This ensures that the supplier is entirely responsible for delivering, installing and commissioning a room in accordance with the tender specification. In such cases it is essential to write the tendering documents so that the detailed responsibilities of both parties are very clearly defined. Disputes are inevitable if this does not happen. A workable allocation of responsibilities is outlined below:
- a) **Client.** The client organization prepares the space for the cold store and provides electrical power and drainage points within the space. Details of the space are given to the cold store installer at the tendering stage.
 - b) **Installer.** The installer inspects the space allocated for the cold store before installation begins and indicates any defects or omissions that need to be rectified.
 - c) **Client.** The client organization corrects these defects or omissions within a previously agreed period.
 - d) **Installer.** The installer reinspects the space and installs and commissions the cold store. At or before the time of handover the installer runs a training course in order to ensure that the client's staff are able to operate the equipment correctly.
3. **Split responsibility.** If no cold store supplier is able to install the equipment this work has to be done by a local contractor appointed by the client organization. In this event it is strongly recommended that a technical representative of the supplier supervise the installation and commissioning of the store. However, split responsibility should be avoided if possible.

9.3 Spare parts

Ensure that the tendering documents specify an adequate quantity of spare parts. What is adequate depends very largely on whether the cold chain equipment supplier has a service and distribution network in the country concerned. It also depends on the funding arrangements. If a donor is paying for the equipment it may be easier to fund a generous supply of spare parts at the time of the original order than to obtain additional funding for spare parts at a later date. A five-year supply is a sensible allowance if there is no local source. The location and management of spare parts must also be considered.

9.4 Commissioning

At least 10% of the payment due to the cold store installer should be withheld until a full commissioning test has been completed satisfactorily. The test procedure should run for at least 48 hours. The appropriate running tests should be repeated for both refrigeration units.

Typical commissioning tests

Cool-down time: Start the refrigeration unit when the room is empty and the same temperature exists inside and outside the room. Keep the cold room door closed during the test. Record the time needed for the internal temperature to drop below +8°C. Run the test for at least 48 hours.

Running test: Record the number of hours that the compressor runs with the door closed and the room empty. Monitor the internal and external temperatures, the evaporator and condenser temperatures, and the pressures of the system. Measure the maximum temperature difference in the cold room and record the locations of any warm and cold spots.

Temperature-rise test: Cut off the electricity supply to the room and measure the period required for the internal temperature to rise to 5°C above the normal operating temperature.

Control and monitoring equipment tests: Test the operation of the automatic duty-sharing, temperature control and temperature-monitoring and alarm equipment. If computerized temperature monitoring is used, load, configure and test the software.

Stand-by generator operation test: Check the power output of the stand-by generator and the operation of the automatic mains failure control system. Run the generator continuously for 48 hours under load.

9.5 Training

Staff must be adequately trained in the use of the equipment. The cold store installer must provide a user training course. If there is no maintenance agreement the installer should also organize a technicians' training course. In addition, see *User's handbook for vaccine cold rooms or freezer rooms* (WHO/V&B/02.31) and its companion volume *How to look after a cold room or freezer room: self-assessment tool* (WHO/V&B/02.30), which provide more general training material on cold store maintenance and vaccine management.

9.6 Maintenance contracts

The maintenance of refrigerators, freezers and cold stores may be carried out by cold chain technicians employed by health ministries, government or parastatal maintenance organizations, or private sector service organizations.

In all cases there must be a reporting system for recording breakdowns and monitoring the effectiveness of repair procedures. A written service agreement should be drawn up with the service provider, covering the following matters.

- **Period of agreement.** Agreements should have a defined term and a legal and financial mechanism for ending the contract in the event of non-compliance by either party.
- **Ownership and location of spare parts.** Decide whether spare parts are to be purchased by the service agency or the immunization service, and where they are to be stored.

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- **Preventive maintenance regime.** Cold stores and other key cold chain equipment must be inspected and serviced regularly in order to ensure correct functioning. The frequency of the inspections and the nature of the work to be carried out must be defined.
 - **Service response rate.** Define acceptable service response rates in the event of equipment failure. There may be several levels. For example, the service response requirement for a primary or higher-level intermediate store may be more stringent than the response requirement at a remote district store.
 - **Sanctions in cases of non-compliance.** Define the financial or administrative penalties that can be applied if the performance of the maintenance agency is inadequate. This may be difficult in cases where a government body is used. However, it is important to ensure that some effective sanction can be exercised, otherwise the service agreement is worthless.
 - **Payment terms.** The possibilities include an annual service fee, payment for parts and labour, payment for labour only, or some combination of these. In the case of a government agency an internal market arrangement must be established.

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Annex 1:

Improving existing cold stores

The performance of an existing cold store can often be improved. The following items should be checked.

Temperature control

The temperature in a +2°C to +8°C cold room should not be lower than +2°C or higher than +8°C at any point. The temperature in a freezer room should remain between -15°C and -25°C throughout. Check the temperature at several places in the room with a thermometer. Note that the WHO recommendation on above-zero vaccine storage has changed. Equipment, controls and alarms may need to be adjusted in order to ensure that temperatures below +2°C do not occur.

Carry out the following checks and rectify any defects.

- Ensure that the thermostat is functioning and correctly adjusted.
- Ensure that the door fits tightly.
- Ensure that the compressor room is well ventilated. A hot compressor room reduces the performance of the cold store.
- Ensure that no part of the cold store or its machinery is exposed to strong sunlight. If it is, install shading screens.
- Service the cooling unit. Check that the refrigerant charge is adequate and that the circuit is not leaking. Replace any defective parts.
- Ensure that the space where the cold store is located is not too hot. If it is, arrange adequate ventilation or air-conditioning.

Check the temperature again. If it remains too high the refrigeration unit may not be powerful enough. Alternatively, the insulation may be inadequate or wet. In order to rectify these problems it is necessary to obtain specialist advice.

Monitoring and security equipment

The following equipment should be installed with every cold store that is intended to hold a large quantity of vaccine.

- A continuous temperature monitoring device.
- An alarm system.
- A stand-by refrigeration system.
- A stand-by electricity supply.

Annex 2:

The “shake test”

Purpose: The shake test is designed to determine whether adsorbed vaccines (DPT, DT, Td, TT or hepatitis B) have been frozen. After freezing, the vaccine is no longer a uniform cloudy liquid, but tends to form flakes which gradually settle to the bottom after the vial has been shaken. Sedimentation occurs faster in a vaccine vial which has been frozen than in a vaccine vial from the same manufacturer which has never been frozen.

Note that individual batches of vaccine may behave differently from one another. Therefore the test procedure described below should be repeated with all suspect batches. In the case of international arrivals, the shake test should be conducted on a random sample of vaccine. However, if there is more than one lot in the shipment, the random sample must include a vial taken from each and every lot.

Test procedure:

1. *Prepare a frozen control sample:* Take a vial of vaccine of the same type and batch number as the vaccine you want to test, and made by the same manufacturer. Freeze the vial until the contents are solid, and then let it thaw. This vial is the *control sample*. Clearly mark the vial so that it cannot later be used by mistake.
2. *Choose a test sample:* Take a vial of vaccine from the batch that you suspect has been frozen. This is the *test sample*.
3. *Shake the control and test samples:* Hold the control sample and the test sample together in one hand and shake vigorously for 10-15 seconds.
4. *Allow to rest:* Leave both vials to rest.
5. *Compare the vials:* View both vials against the light to compare the sedimentation rate. If the test sample shows a much slower sedimentation rate than the control sample, the test sample is probably potent and may be used. If the sedimentation rate is similar and the test sample contains flakes, the vial under test has probably been damaged by freezing and should not be used. Note that some vials have large labels which conceal the vial contents. This makes it difficult to see the sedimentation process. In such cases, turn the sample and reference vials upside down and observe sedimentation taking place in the neck of the vial.

Subsequent action: If the test procedure indicates that the test sample has been damaged by freezing, you should notify your supervisor immediately. Standard Operating Procedures should then be followed to ensure that all damaged vaccine is identified and that none of this damaged vaccine is distributed or used.

The Department of Vaccines and Biologicals was established by the World Health Organization in 1998 to operate within the Cluster of Health Technologies and Pharmaceuticals. The Department's major goal is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases.

Five groups implement its strategy, which starts with the establishment and maintenance of norms and standards, focusing on major vaccine and technology issues, and ends with implementation and guidance for immunization services. The work of the groups is outlined below.

The *Quality Assurance and Safety of Biologicals team* ensures the quality and safety of vaccines and other biological medicines through the development and establishment of global norms and standards.

The *Initiative for Vaccine Research* and its three teams involved in viral, bacterial and parasitic

diseases coordinate and facilitate research and development of new vaccines and immunization-related technologies.

The *Vaccine Assessment and Monitoring team* assesses strategies and activities for reducing morbidity and mortality caused by vaccine-preventable diseases.

The *Access to Technologies team* endeavours to reduce financial and technical barriers to the introduction of new and established vaccines and immunization-related technologies.

The *Expanded Programme on Immunization* develops policies and strategies for maximizing the use of vaccines of public health importance and their delivery. It supports the WHO regions and countries in acquiring the skills, competence and infrastructure needed for implementing these policies and strategies and for achieving disease control and/or elimination and eradication objectives.

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