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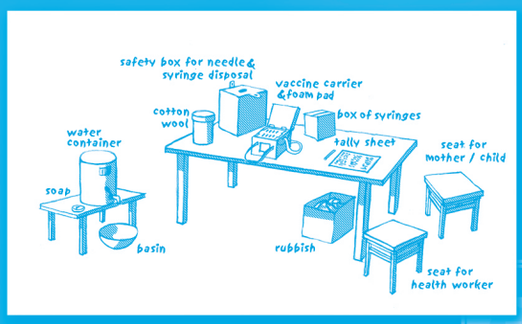
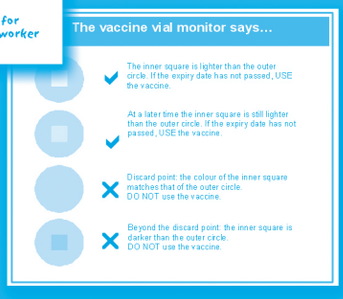
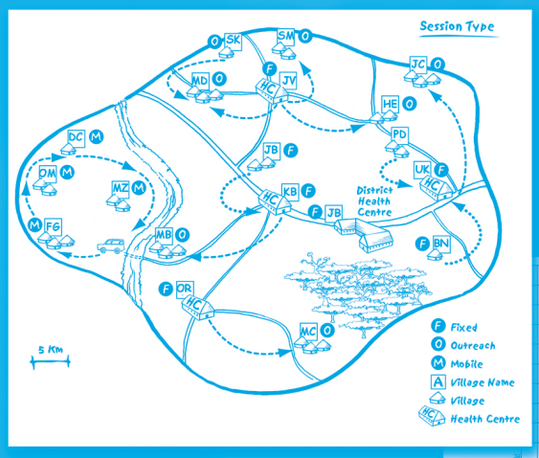
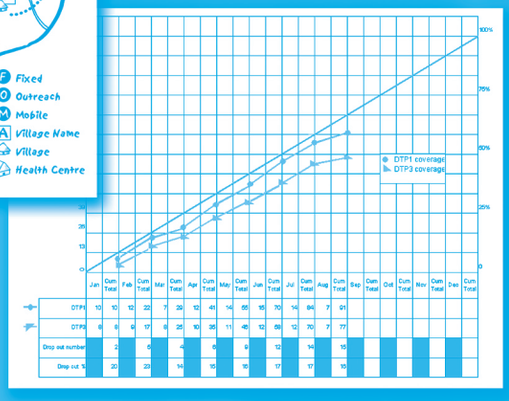
Training for mid-level managers (MLM)

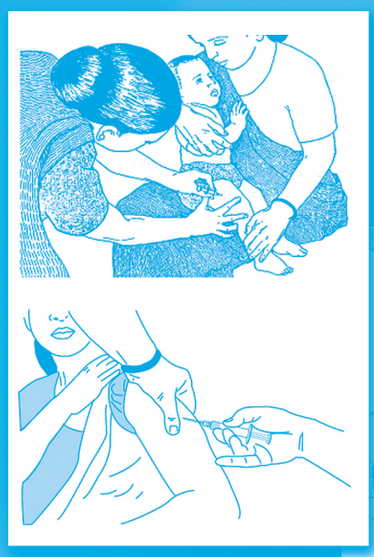
I. Cold chain, vaccines and safe-injection equipment management











- *Estimating needs*
- *Storage*
- *Distribution and transport*
- *Monitoring and supervision*

Immunization, Vaccines and Biologicals

World Health Organization

Training for mid-level managers (MLM)

Module 1 : Cold chain, vaccines and safe-injection equipment management

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Introduction to the series

This new series of modules on immunization training for mid-level managers replaces the version published in 1991. As there have been many changes in immunization since that time, these modules have been designed to provide immunization managers with up-to-date technical information and explain how to recognize management and technical problems and to take corrective action and how to make the best use of resources.

More and more new, life-saving vaccines are becoming available, yet the introduction of a new vaccine does not necessarily require a separate plan and separate training. This new series for mid-level managers integrates training for new vaccine introduction into each subject addressed by the modules. In this way, introduction of new vaccines is put into its day-to-day context as part of the comprehensive range of activities required to improve immunization systems.

In the context of these modules, mid-level managers are assumed to work in secondary administrative levels, such as a province; however, the modules can also be used at national level. For district managers (third administrative level), a publication on 'immunization in practice'[1] is widely available. As it contains a large amount of technical detail, it is also recommended for mid-level managers courses.

In writing these modules, the authors tried to include essential topics for mid-level managers, while keeping the modules brief and easy to use. They are intended to complement other published materials and guidelines, some of which are referred to in the text. Many more documents are available on the CD-ROM which accompanies this series. Each module is organized in a series of steps, in which technical information is followed by learning activities. Some knowledge and experience are needed to complete the learning activities, but even new readers should be imaginative and constructive in making responses. Facilitators should also be aware that the responses depend on the national context. Thus, there are no absolutely right or wrong answers, and the series does not set down new 'policies' or 'rules'. The authors hope that the readers of these modules will find them informative, easy to read and an enjoyable learning experience.

Modules in the mid-level managers series

Module 1 : Cold chain, vaccines and safe-injection equipment management
Module 2 : Partnering with communities
Module 3 : Immunization safety
Module 4 : Supportive supervision
Module 5 : Monitoring the immunization system
Module 6 : Making a comprehensive annual national immunization plan and budget
Module 7 : The EPI coverage survey
Module 8 : Making disease surveillance work

[1] *Immunization in practice : A practical guide for health staff.* Geneva, World Health Organization, 2004

Acknowledgements

This new series of modules on immunization training for mid-level managers is the result of team work between a large number of partners including the Centers for Disease Control and Prevention (CDC), IMMUNIZATIONbasics, Program for Appropriate Technology in Health (PATH), United Nations Children's Fund (UNICEF), United States Agency for International Development (USAID) and the World Health Organization (WHO). The authors are especially grateful to the consultants from the University of South Australia who have made a major contribution to the development of the modules.

Contents

Abbreviations and Acronyms

The following abbreviations have been used in this document.

AD	auto-disable (syringe)
BCG	bacille Calmette-Guérin (vaccine)
DT	diphtheria–tetanus (vaccine)
dT	children's dose of diphtheria and tetanus toxoids
DTP	diphtheria–tetanus–pertussis vaccine
EEFO	earliest expiry first out
EPI	Expanded Programme on Immunization (WHO)
HepB	hepatitis B vaccine
Hib	*Haemophilus influenzae* type b (vaccine)
ILR	ice-lined refrigerator
JE	Japanese encephalitis
MMR	measles–mumps–rubella vaccine
MR	measles–rubella vaccine
OPV	oral polio vaccine
Td	tetanus and diphtheria toxoids with reduced diphtheria content for adults
T-series	tetanus-containing vaccines
TT	tetanus toxoid
VVM	vaccine vial monitor
WMF	wastage multiplication factor
YF	yellow fever

Introduction to Module 1

Purpose of this module

As a mid-level manager do you know the status of vaccine and safe-injection supplies in every district of your province? How would you adapt your cold chain and safe-injection supply system in the context of changing programme needs, such as a change in vaccine presentation, ageing equipment or the planned introduction of a new vaccine? Do you know how to implement a reliable bundling policy in your province?

The purpose of Module 1 is to help you determine how much vaccine and safe-injection equipment you need to run your immunization programme, how to manage its storage, distribution and replacement, how to monitor the system, and how to respond to changes when a new vaccine is introduced.

Knowledge of Module 1 will help you to be aware of the current status of supplies at every level and be able to respond to needs, thereby avoiding a shortage or over-supply.

Module 1 combines training for the management of the cold chain, vaccine and safe-injection equipment. Much has been written in detail elsewhere and many documents are available on these subjects. This module does not, therefore, aim to provide comprehensive or detailed guidelines on every issue; rather, it explains the relevant management aspects as they relate to the everyday experience of a mid-level manager. Annex 1 provides a comprehensive list of useful resources and subsequent annexes contain extracts from a number of key references.

WHO and UNICEF recommend that managers always order and supply vaccines **bundled** with safe-injection equipment. This module refers to diluents, auto-disable (AD) syringes, reconstitution syringes and safety boxes as "safe-injection equipment" and incorporates the principle of **bundling** – that is, that vaccines and safe-injection equipment are always available together, in corresponding quantities, at each level of the supply chain.

Module 1 covers the following four steps:

Estimating needs > **Storage** > **Distribution and transport** > **Monitoring and supervision**

1. Estimating vaccine and safe-injection equipment needs

The availability of an adequate supply of vaccines, diluents and safe-injection equipment of assured quality is critical to every immunization service. Effective management and storage of supplies can help save on programme costs, prevent high wastage rates and stock-outs, and improve the safety of immunizations.
This section outlines two methods that are commonly used to estimate vaccine and safe-injection equipment needs at the provincial level.

1) Estimating vaccine and injection equipment needs based on the **target population.**
2) Estimating vaccine and injection equipment needs based on **previous consumption.**

Although both methods rely on data from the service-delivery level, the first method is preferred since it is more accurate. A third method – estimating vaccine and injection equipment needs based on the number and type of sessions planned – is not described here as it is more suitable for planning at lower levels such as the district and health-facility level. See *Immunization in practice: A practical guide for health staff* (Geneva, World Health Organization, 2004).

Whichever method is used, the accuracy will depend on the quality of the data used and the knowledge of the person doing the calculations.

1.1 Estimating vaccine and safe-injection equipment needs based on target population

A number of basic parameters are necessary to estimate vaccine and safe-injection equipment needs based on the target population, including:

- the target population of the area (such as infants or pregnant women);
- details of vaccines included in the national immunization schedule, including the number of doses and the number of doses per vial;
- the wastage multiplication factor (WMF) for each vaccine and the AD syringes (see Box 1.1 for details).

Table 1.1, and the instructions below, show how this information can be used to estimate vaccine and safe-injection equipment needs.

Table 1.1: Estimating annual vaccines and safe-injection equipment requirements for a province with a target population of 100 000 infants and pregnant women

	Vaccines	Target population	Number of doses	Doses per vial	WMF	Doses needed	WMF syringes	0.05 ml AD syringes	0.5 ml AD syringes	2 ml reconstitution syringes	5 ml reconstitution syringes	Safety boxes
	A	B	C	D	E	F=B*C*E	G	H=B*C*G	I=B*C*G	J=F/D	K=F/D	L=(H+I+J+K)/100
Vaccines	OPV (oral)	100 000	4	20	1.33	532 000	1.11					
	TT	100 000	2	10	1.33	266 000	1.11		222 000			
	BCG	100 000	1	20	2.00	200 000	1.11	111 000		10 000		
	Measles	100 000	1	10	1.33	133 000	1.11		111 000		13 300	
	Hib	100 000	3	2	1.05	315 000	1.11		333 000	157 500		
	DTP-HepB	100 000	3	2	1.05	315 000	1.11					
Diluents	for BCG	100 000	1		2.00	200 000	1.11					
	for Measles	100 000	1		1.33	133 000	1.11					
	Total							**111 000**	**666 000**	**167 500**	**13 300**	**9 578**
	DTP-HepB-Hib	100 000	3	1	1.05	315 000	1.11		333 000			
	Total							**111 000**	**666 000**	**10 000**	**13 300**	**8 003**

In the above example in addition to other vaccines, two different formulations of pentavalent vaccine are considered:

a) DTP-HepB+Hib in a **two-dose formulation**, where the freeze-dried Hib component is reconstituted with the liquid DTP-HepB using a 2 ml reconstitution syringe;

b) DTP-HepB-Hib in a **single-dose** liquid formulation that requires no reconstitution syringe.

Table 1.1 is constructed as follows.

Column A: Include all vaccines currently in the schedule.

Column B: Insert the target population for each vaccine.

Column C: List the number of doses of each vaccine that each infant and pregnant woman should receive.

Column D: Include the number of doses per vial for each vaccine, according to the presentation being used.

Column E: List the WMF for each vaccine.

Column F: Calculate the number of doses needed, based on the target population (100%), the number of doses and the WMF (B x C x E).

Column G: List the WMF for syringes (estimated to be 1.11 for all types).

Column H and I: Calculate the number of AD syringes needed, based on the target population, the number of doses and the WMF for syringes (B x C x G). (Only BCG vaccine uses a 0.05 ml syringe.)

Column J and K: Calculate the number of syringes needed for reconstitution, based on the number of doses needed and the number of doses per vial.

Column L: Calculate the number of safety boxes required, based on the total number of syringes (H+I+J+K)/100. This method provides a way of planning your needs; however, during distribution you must ensure that each facility (especially the smaller ones) has enough boxes.

Assumption 1: *Two different formulations of pentavalent vaccine are used (see previous page).* In DTP-HepB+Hib vaccine, the freeze-dried Hib component is reconstituted with DTP-HepB, while DTP-HepB-Hib is a liquid vaccine, its five components mixed together in the one vial.

Assumption 2: *A birth dose of oral polio vaccine (OPV) is included in the schedule.*

Assumption 3: *The WMF for safe-injection equipment is 1.11 (see Box 1.1).*

Assumption 4: *One safety box holds 100 syringes.*

Assumption 5: *The manager aims to reach every eligible infant and pregnant woman in the target population.*

Box 1.1: How do I calculate the wastage multiplication factor (WMF)?

The vaccine wastage factor indicates how much additional vaccine should be ordered in order to allow for the given wastage rate.

The vaccine wastage rate can vary greatly according to several characteristics of the programme – for example session sizes, session plans, vial presentation and supply management.

The following formula shows the relationship between the vaccine wastage rate and the WMF.

$$\text{WMF} = \frac{100}{100 - \text{wastage rate}}$$

Example: Let us assume the wastage rate of a particular antigen is 50%. Using the formula above:

$$\text{The WMF would be } \frac{100}{100\text{-}50} = 2$$

That means, for every dose of this particular antigen administered, the mid-level manager should anticipate 2 doses to compensate for the 50% wastage.

The table below is a quick reference guide to the common wastage rates and their corresponding WMFs.

Wastage rate	5%	10%	15%	20%	25%	30%	35%	40%	45%	50%
WMF	1.05	1.11	1.18	1.25	1.33	1.43	1.54	1.67	1.82	2

1.2 Estimating vaccine and safe-injection equipment needs based on previous consumption

Each parameter relative to previous consumption can be affected by many factors, especially programme performance, during the supply period in question. Estimating needs based on previous consumption may, therefore, not be as reliable as the method based on target population.

In most provinces, vaccine and safe-injection equipment are supplied regularly – for example, every three months (January, April, July and October).

Consider the following measurements when estimating vaccine and safe-injection equipment needs based on previous consumption:

- initial stock (vaccines and safe-injection equipment) at the beginning of the given period;
- stock received during the period;
- stock at the end of the period.

Other issues to consider include stock wasted during the same period (i.e. unopened vials that have expired or been frozen, broken or gone missing). If a substantial number of unopened vials have been wasted during the previous period, they need to be replaced. Any additional special activities planned for the forthcoming supply period should also be considered.

Example: Let us assume that a province receives vaccine and safe-injection equipment supplies every three months (January, April, July and October). It is now the end of June and the province wants to estimate OPV vaccine needs for the next three months, based on previous consumption. No supplementary immunization activities using OPV are planned during this period.

The data required for estimating needs on the basis of previous consumption are:

OPV vaccine balance at the beginning of April = 10 000 doses;

OPV vaccine received during April-June = 50 000 doses;

OPV vaccine balance at the end of June = 20 000 doses.

Vaccine needs	=	starting stock balance	+	stocks received	+	new plans	- end stock balance
	=	10 000	+	50 000	+	0	- 20 000
	=	40 000 OPV doses based on doses previously consumed					

40 000 doses of OPV should therefore be ordered for July, August and September.
This process should be repeated every quarter (or equivalent supply period).

Note: This method automatically considers vaccines that have been wasted during the previous period so there is no need to include the WMF.

2. Storage of vaccines and safe-injection equipment

This section takes you through a series of steps on how to select and maintain cold-chain equipment, how to estimate the total volume of vaccines and safe-injection equipment to be stored and how to manage the storage of these items.

2.1 Storing vaccines

2.1.1 Vaccine storage conditions

Temperature sensitivity of vaccines

WHO recommends the range of temperatures for storing and transporting vaccine on the basis of data supplied by manufacturers. Each vaccine has its own specific storage requirements so it is extremely important to know how long, and at what temperature, each vaccine can be stored.

All vaccines can be stored at positive temperatures (between +2 °C and +8 °C). However only *some* vaccines can be stored at negative temperatures (between -15 °C and -25 °C).

Table 1.2 lists the recommended storage conditions for most Expanded Programme on Immunization (EPI) vaccines.

Loss of potency due to heat

Vaccines that have been exposed to temperatures above +8 °C may lose their potency over time. The vaccine vial monitor (VVM) must always be used to guide decisions on the use of vaccine.

Freezing

The "T-series" of vaccines (DTP, DT, dT, Td, TT), HepB, liquid Hib and liquid pentavalent vaccine should always be stored between +2 °C and +8 °C as they are damaged by freezing; they may also be damaged by *exposure* to freezing temperatures. HepB is the vaccine most sensitive to freezing temperatures. The most common cause of exposure to freezing temperatures is the failure to correctly condition ice packs prior to transport. To reduce the overall risk of freeze damage to vaccines, programmes should follow the best practices as outlined in the *Aide-memoire for prevention of freeze damage to vaccines* (WHO/IVB/07.09). If it is suspected that vaccines have been exposed to freezing temperatures, perform the "shake test" (see Annex 3) before deciding whether to use the vaccine or not. A VVM does not indicate if a vaccine has been frozen.

Key point: Damage can occur if a vaccine is exposed to temperatures outside its correct storage range. Just by looking at the physical appearance of the vaccine may not tell you if it has been damaged since it can remain visibly unchanged. Once a vaccine has been damaged it is not possible to recover its potency.

Table 1.2: Recommended temperatures and length of storage at various levels of the cold chain

Vaccines	Primary (national) stores	Intermediate stores		Health facility	Health post
		Province	District		
	Maximum duration of storage			Maximum duration of storage	
	6–12 months	Maximum 3 months	1–3 months	1 month or less	according to session plan
OPV	Store at -15 °C to -25 °C. OPV is the only vaccine that can safely be frozen and unfrozen repeatedly .			Store at +2 °C to +8 °C	
BCG Measles MMR MR Yellow fever Hib lyophilized Meningitis JE	Store these lyophilized vaccines at +2 °C to +8 °C. Under exceptional circumstances they can be temporarily stored at -15 °C to -25 °C (e.g. if there is a temporary shortage of storage space). Never freeze diluent.			Store at +2 °C to +8 °C	
Hepatitis B DTP-HepB DTP-HepB-Hib liquid Hib liquid DTP DT/TT/Td Pneumococcal Rotavirus	Store at +2 °C to +8 °C. Never freeze.				

Diluent

If diluent is *included* in the vaccine packaging, store it between +2 °C and +8 °C. However, if diluent is *supplied separately*, it can be stored outside the cold chain but must be cooled before use, preferably for a day or for a period of time sufficient to ensure that the vaccine and diluent are both at temperatures between +2 °C and +8 °C when they are reconstituted. Never freeze diluent.

Length of storage and expiry date

The suggested maximum length of storage is 6–12 months at national level, 3 months at provincial level, 1–3 months at district level and 1 month or less at health-facility level. Also keep in mind that the VVM status and expiry dates of vaccines must be monitored and respected.

Each vial shows an expiry date. Never use vaccines when the expiry date has passed, even if the VVM shows no heat damage. In general, always apply the earliest-expiry-first-out (EEFO) principle.

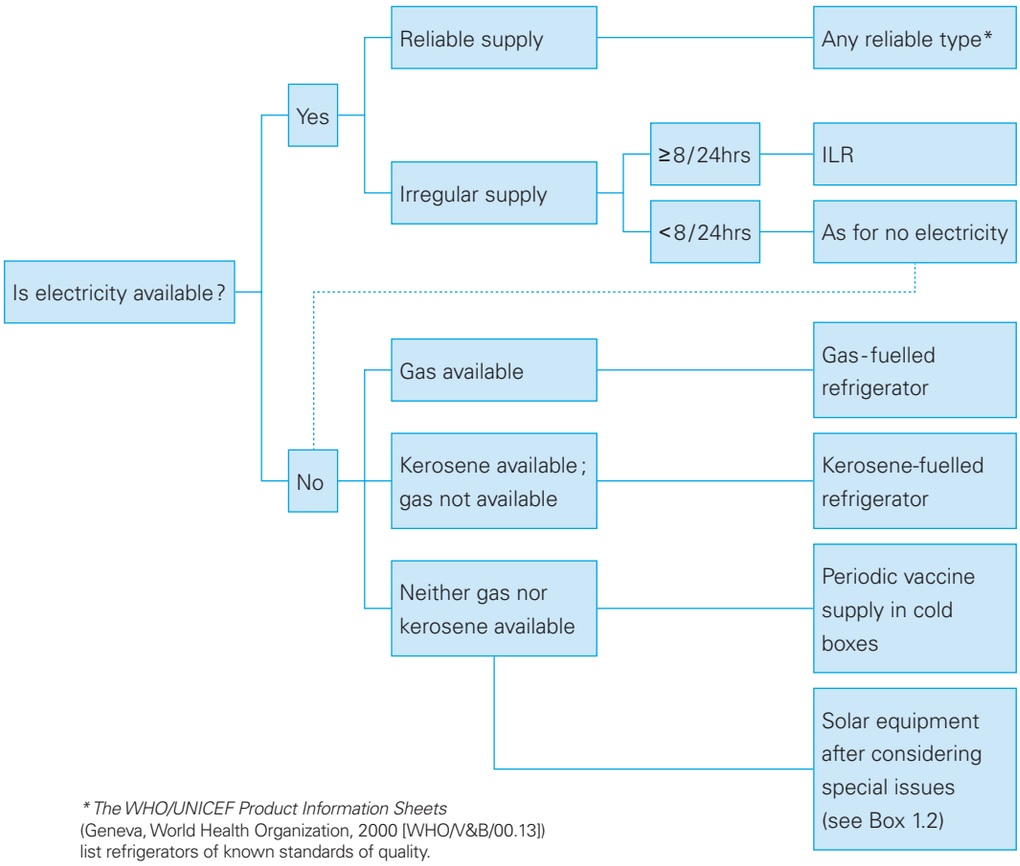
Photosensitivity

Some vaccines are very sensitive to light and their exposure to ultraviolet light causes loss of potency. BCG, measles, MR, MMR and rubella vaccines are equally light-sensitive and must always be protected from sunlight and fluorescent (neon) light. Some manufacturers provide these vaccines in vials made of a darker glass.

2.1.2 Selecting appropriate cold-chain equipment

Make the decision on what type of cold-chain equipment to use on detailed knowledge of the local situation. The first question to ask is whether or not reliable electricity is available. If it is available, whether from a grid or a generator, various types of electric refrigerator can be used, provided they are of known reliability. Figure 1.1 shows a simple flowchart to make decisions on selecting cold-chain equipment using basic criteria.

Figure 1.1: Simple flowchart to help decision-making in selecting refrigeration equipment



** The WHO/UNICEF Product Information Sheets* (Geneva, World Health Organization, 2000 [WHO/V&B/00.13]) list refrigerators of known standards of quality.

In areas with an electricity supply of 8 or more hours during a 24-hour period (whether the source is grid and/or generator), the ice-lined compression refrigerator is highly suitable because it has a holdover time of 24 hours at +43 °C ambient temperature; it can therefore prevent vaccines from damage during power interruptions or regular outages.

In areas with less than 8 hours of electricity during a 24-hour period, the decision will rest on the type of fuel to use. If gas is available, gas-fuelled absorption refrigerators are preferred. They are cleaner to use, easy to maintain and running costs are almost the same as for electric refrigerators. Where gas is not available, kerosene-fuelled refrigerators are the next option. They require more maintenance, however, and are less reliable. Solar refrigerators are also an option but special issues need to be considered prior to introducing them (see Box 1.2 for further discussion on this topic).

A decision also needs to be taken on what equipment is needed to freeze ice packs for keeping vaccine cool in the vaccine carriers. Some types of refrigerator include a separate freezer compartment but, depending on the capacity required, it may also be necessary to use separate freezer equipment or designated ice pack freezers.

Box 1.2: What are the special issues concerning solar-powered refrigerators?

Solar powered refrigerators are often proposed for remote areas that have no access to power grids, gas or kerosene. This can be an excellent solution; however, experience in developing countries over many years has shown that there are several issues to consider before choosing solar power, including:

- the high initial cost: purchase price and installation costs;
- the high cost of battery and regulator replacement: batteries need to be replaced every two to three years;
- the daily attention that must be given to battery condition and cleaning the solar panels;
- the high maintenance repair costs: specialized technical support is needed;
- security issues as many solar powered systems are target for robbery.

In situations where a number of different types of refrigerator could be used, consider all the advantages and disadvantages that may help with the decision-making process. Tables 1.3, 1.4 and 1.5 compare the different types of refrigerators.

More detailed information on choosing equipment is given in the *Guideline for establishing or improving primary and intermediate vaccine stores* (Geneva, World Health Organization, 2002 [WHO/V&B/02.34]). Information from manufacturers can also be of assistance in choosing equipment since they can usually provide detailed specifications on their own appliances.

When you decide to buy a certain type of refrigerator, keep in mind the following issues that are relevant to all cold-chain equipment:

- budgeting for fuel (gas or kerosene) or electricity;
- planning the distribution of gas cylinders or kerosene;
- establishing the expected quantities of consumption of gas or kerosene;
- planning for periodic replacement of other consumables (e.g. wicks in kerosene-fuelled refrigerators) and other spare parts;
- training of the local health worker in regular preventive maintenance.

Considering an alternative to continuous refrigeration

In areas with no electricity and/or poor access to gas or kerosene, a cold-box system with regular supply and storage of vaccines for short periods offers some advantages over trying to provide continuous refrigeration. Vaccine can be periodically (for example monthly) supplied to health facilities in cold boxes with conditioned ice packs and used over a period of several days according to the recommended holdover time and condition of VVM (while ensuring that vaccine is not exposed to extreme temperatures in this process); this may be sufficient to provide an adequate number of immunization sessions in an area.

Table 1.3: Advantages and disadvantages of different refrigerator types (based on energy source)

Type of refrigerator	Advantages	Disadvantages
Electric (compression type)	• Easy to maintain. • Purchase costs less than for absorption type. • Cools more quickly than absorption type. • Expertise widely available for repair.	• Requires continuous source of electricity except for ice-lined type that requires 8 hours in 24 hours.
Gas (absorption type)	• Flexible energy source; gas models are designed to work with either gas or electricity. • Useful for places without regular electricity supply.	• More expensive than compression type to purchase. • Needs more attention and maintenance than electricity-powered type. • Cools more slowly than electricity-powered type. • Depends upon a reliable gas-distribution network.
Kerosene (absorption type)	• Flexible energy source; kerosene models can work with kerosene or electricity. Useful for places without regular electricity supply. • Kerosene is widely available.	• More expensive than compression type to purchase. • Difficult to maintain and needs constant supply of parts (e.g. wicks). • Cools more slowly than electricity-powered type. • Poor quality kerosene can impede function. • Limited temperature control.
Solar (compression or absorption type)	• Works without any traditional energy source. • Environmentally friendly.	• High initial cost. • Requires specialized maintenance that is often not available in many countries. • Frequent maintenance, high recurrent costs for replacement batteries.

Table 1.4: Advantages and disadvantages of different refrigerator types (based on layout)

Type of refrigerator	Advantages	Disadvantages
Front-opening	• Loading and unloading is easier than with top-opening.	• Holdover time is shorter compared to top-opening. • Chances of vaccine freezing at the cool air outlet/evaporator. • Temperature inside the refrigerator will increase more rapidly when the door is opened.
Top-opening	• Holdover time is longer than for front-opening if door is opened frequently. • More economic use of space.	• Vaccine freezing may occur at the bottom of the refrigerator if it is not loaded correctly. • Loading and unloading is less convenient than with a front-opening unit.

Table 1.5: Advantages and disadvantages of different refrigerator types (based on lining)

Type of refrigerator	Advantages	Disadvantages
Ice-lined refrigerator	• Maintains appropriate internal temperatures with only 8 hours of electricity in 24 hours in most conditions.	• More chances of vaccine freezing on sides and at the bottom of the refrigerator if it is not loaded correctly.
Non ice-lined	• Cheaper to purchase.	• Shorter holdover time.

Learning activity 1.1: Problems encountered when using and maintaining the cold chain.

TASK 1. From your own experience: a) list two major problems you have encountered when using the refrigerator types listed below, then b) list the solutions that you have tried or would like to try.

Type of refrigerator	Problems encountered	Solutions – tried or proposed
ILR		
Gas		
Kerosene		
Solar		

2.1.3 Cold-chain maintenance, repair and replacement

Maintenance of equipment

In addition to installing the best suited cold-chain system for an area, the cold-chain equipment will need periodic repairs, replacements and servicing to ensure vaccines are stored at recommended temperatures.

The responsibilities of the staff in the facility where the cold-chain equipment is located include:

- control and monitoring of the temperature;
- arrangement of vaccines, diluents and ice packs (for further details see *Immunization in practice: A practical guide for health staff*. Geneva, World Health Organization, 2004);
- general maintenance (including cleaning and defrosting, trimming the wick);
- recording and reporting temperatures.

Table 1.6 below shows how these tasks can be arranged according to a schedule of key activities.

Table 1.6: Key activities and maintenance tasks to ensure proper use of the cold chain

Key activities	Daily tasks	Weekly tasks	Monthly tasks
Control and monitoring of the temperature.	• Check and record temperature twice a day (morning and evening). • Check the flame quality and adjust (gas and kerosene).	• Analyse the trend of the temperature chart. • Discuss any abnormalities in the expected pattern with your supervisors.	• Analyse the trend of the temperature chart. • Discuss any abnormalities in the expected pattern with your supervisors.
Arrangement of vaccines, diluents and ice packs.	• Make sure that vaccines, diluents and ice packs are loaded according to existing national guidelines. • Application of EEFO.	• Check and remove expired stock, including vaccines with VVMs beyond the discard point. • Ensure replacement of stocks.	• Check and remove expired stock, including vaccines with VVMs beyond the discard point. • Ensure replacement of stocks.
General maintenance.	• Clean, dry and store cold boxes and vaccine carriers that have been used during the day. • Check the wick quality; trim the wick if necessary (kerosene).	• Check the availability of fuel (kerosene and gas). • Check if the refrigerator and/or the freezer needs to be defrosted.	• Clean and dry the inside of the refrigerator and/or the freezer. • Clean and wipe the dust off the outside of the refrigerator and/or the freezer.
Reporting.	• Report to the supervisor any problem observed on equipment. • In case of equipment failure, and/or long interruptions of electricity, act according to the emergency plan.		• Complete all the monthly reporting forms according to the instructions and submit them to the next level.

Repair of equipment

Staff can carry out simple repair tasks in the facility where the cold-chain equipment is located. More complex repairs need technical expertise; this may be available locally or may require a visit by a trained technician. Table 1.7 is an example of how the mid-level manager can allocate responsibility for repairing cold-chain equipment to various individuals.

Table 1.7: Repair responsibilities at different levels

Refrigerators requiring replacement parts	Who is responsible for the repair task?			
	Health centre staff	Local technician	Regional technician	Central work-shop
Kerosene refrigerator	Lamp glass Sealing ring Fuse	Burner and modification kit Door seal Heating elements	Tank assembly Doors Thermostat (electric refrigerators)	Cooling unit
Gas refrigerator	Fuse	Jet Gas hose Regulator Door seal	Piezo lighter Flame failure Thermostat Doors	Cooling unit
Electric refrigerator (compression)	Fuse	Thermostat Door seal	Compressor Starting device Overload cut-out	Evaporator Condenser
Solar (photovoltaic) refrigerator	Fuse Distilled water	Door seal	Power regulator Thermostat Compressor controller Cables Battery replacement	Compressor Condenser or cooling unit and all other parts

Replacement of equipment

As a mid-level manager you must be aware of the status of the cold-chain equipment in your area. Conduct a regular, systematic analysis to determine which equipment needs replacing.

Developing a replacement plan will require an inventory of the existing cold chain and management decisions on what type and capacity of equipment is needed. For every cold-chain location it will be necessary to know the population served, the status of electricity or other energy supplies, and the vaccine supply period.

Table 1.8 provides an example of a cold-chain equipment inventory form. This will help you to:

- understand the current status of the equipment;
- plan scheduled replacements;
- make decisions on what kind of replacement equipment to provide.

Table 1.8: An example of a cold-chain equipment inventory form

DISTRICT: KAPPALA **YEAR:** 2006

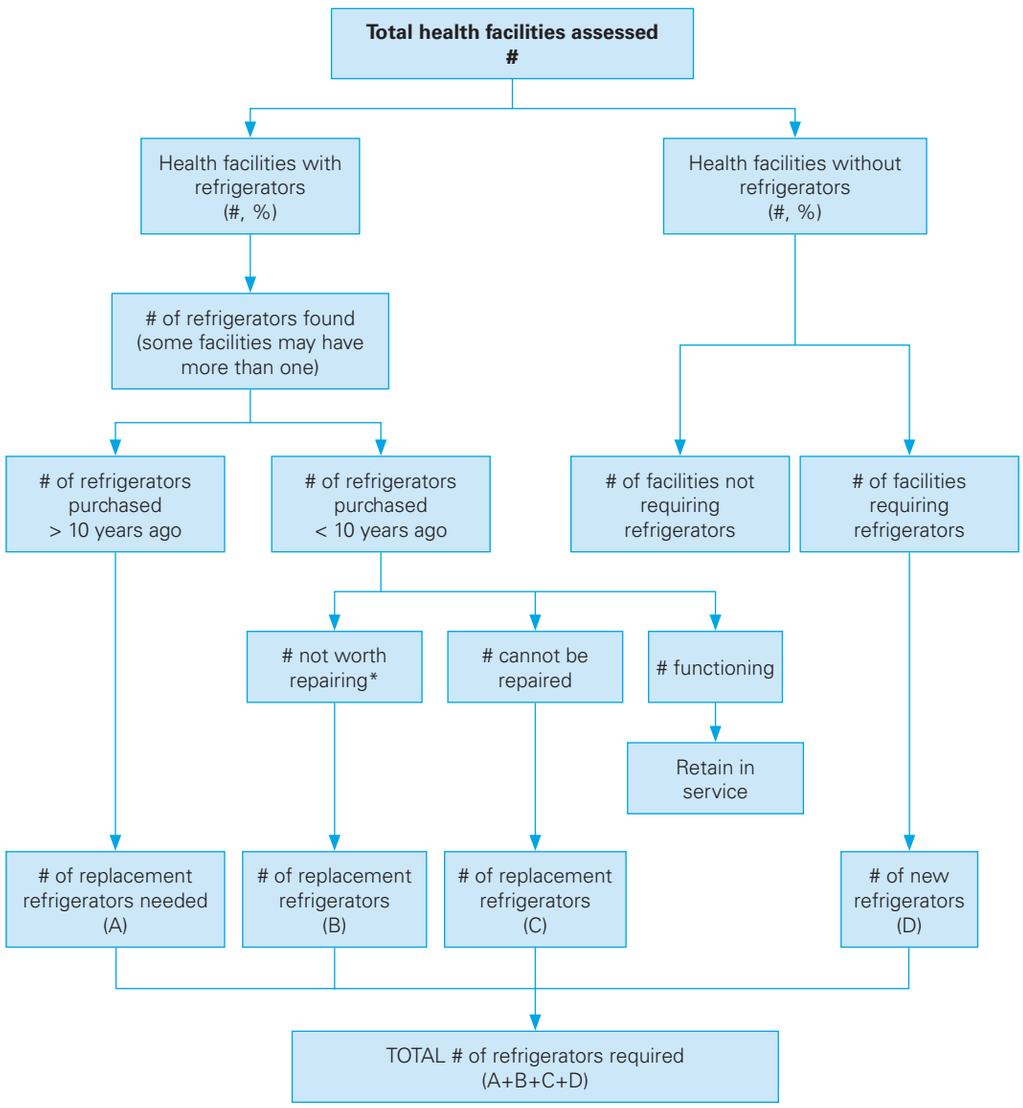
COLD-CHAIN EQUIPMENT INVENTORY												
Information relating to the location					**Information relating to the cold-chain equipment**							
Name	Type of facility	Total population	Electricity (Y/N)	Electricity > 8hrs in 24 hours	Manufacturer	Model	Serial number	Current working status	Date of last assessment	Energy source (G=gas K=kerosene E=electric S=solar)	Year of installation	Year of planned replacement
Mazulo	Clinic	675	N	-	Sibir	V240 GE	234-233-123	good	1/3/2006	G	1996	2006
Kappala	District Health Service	10,000	Y	Y	Vesfrost	MK 214	25632-AA-34	bad	2712/2003	E	1998	2007
Kappala	District Health Service	10,000	Y	Y	Vesfrost	MK 074	9958-4-TO	good	14/08/07	E	2000	2011
Bapun	Clinic	700	N	-	Electrolux	RCW 50 EG	WTB-336	bad	14/8/2007	G	2002	2007

Note: Although this example refers to refrigerators only, cold boxes, vaccine carriers, freezers and other equipment can be added if needed. A blank copy of this form is included in Annex 6.

Key point: Update the cold-chain inventory annually. Plan for the replacement of refrigerators every 10 years.

With good planning and maintenance it is possible to avoid unexpected failures of the cold-chain equipment. As a mid-level manager, you should aim to update the inventory every year and plan both the replacement of old equipment and the establishment of new equipment. Figure 1.2 below shows how the inventory information can be presented in order to calculate the total equipment to be purchased each year. This clear presentation of data will provide important evidence to the national-level managers of the need for new equipment in your province.

Figure 1.2: Flowchart to get an overview of refrigerator requirements

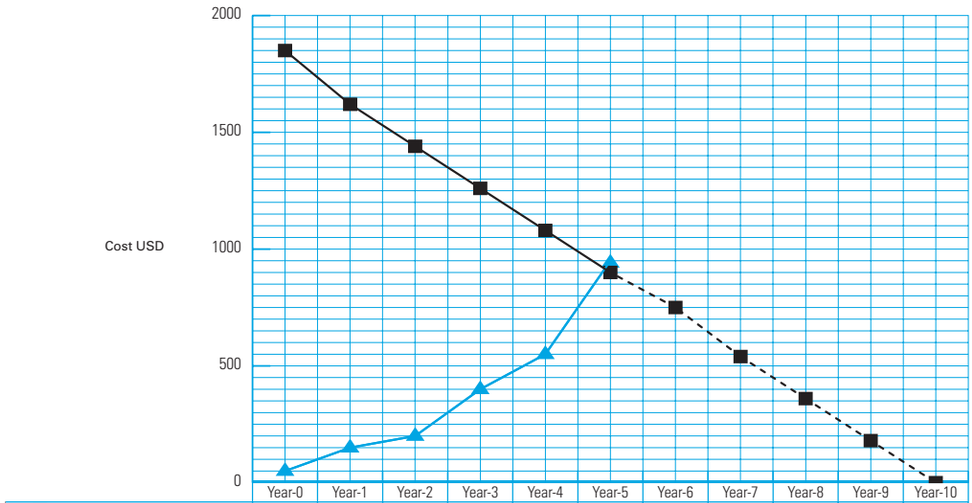


* *See Box* 1.3, *# = number*

Box 1.3: Should I repair or replace?

If a piece of equipment malfunctions or fails completely, the mid-level manager must decide whether to replace or repair it. This can be a difficult decision, especially if it has failed earlier than expected (a cold-chain refrigerator is generally considered to have a lifespan of 10 years). The following statement is a practical rule of thumb to help make the decision on whether to repair or replace: *"When the cumulative repair cost is equal to, or higher than, the depreciated value of the equipment, the recommended practice is to replace rather than repair it."* Figure 1.3 illustrates how to put this rule into practice.

Figure 1.3: Example of equipment replacement point



	Year-0	Year-1	Year-2	Year-3	Year-4	Year-5	Year-6	Year-7	Year-8	Year-9	Year-10
Residual value	1800	1620	1440	1260	1080	900	720	540	360	180	0
Cumulative repair cost	50	150	200	400	500	950					

In the example above:

- the equipment was purchased in Year 0 for US$ 1800 and was expected to have an operational life of 10 years – that is, to have a residual cost of US$ 0 by the end of Year 10, the value of the equipment depreciating every year by US$ 180;
- by Year 5 the cumulative repair costs had reached US$ 950; this exceeded the depreciated (residual) value of US$ 900;
- although theoretically the equipment should last another five years, the best practice would be to replace it immediately because any costly new repair/s would not be viable beyond this point.

Establishment of equipment

The decision to establish new cold-chain storage facilities depends on many local factors such as the size and growth of the population, distance to other facilities as well as accessibility and suitability. Other factors, such as political support or community acceptability for the location, can also play an important role. Once the location has been decided, use the Figure 1.1 flowchart to decide what type of equipment is most suitable, taking into consideration the advantages and disadvantages of each type, as listed in Tables 1.3 to 1.5.

2.2 Storing safe-injection equipment

The optimal storage conditions for safe-injection equipment (such as AD syringes, reconstitution syringes and safety boxes) are more flexible than for vaccines.

2.2.1 Optimal storage conditions for safe-injection equipment

The conditions under which safe-injection equipment (such as AD syringes, reconstitution syringes and safety boxes) can be stored are more flexible than those for vaccines; however, some general guidelines must still be followed in order to avoid contamination and wastage of materials.

The figure below covers some practical measures to ensure optimal storage conditions, such as cleanliness, stock rotation and damp-proofing. Mid-level managers should not only know and understand these principles, but should promote them during supportive supervision visits.

Figure 1.3: Guidelines for proper storage of health commodities

- Clean and disinfect storeroom regularly, to discourage harmful insects and rodents from entering the storage area.
- Store injection safety commodities in a dry, well-lit, well-ventilated storeroom.
- Protect storeroom from dampness.
- Keep functional fire safety equipment available.
- Store latex products away from electric motors and fluorescent lights.
- Limit storage area access to authorized personnel.
- Stack cartons at least 10 cm (4 in.) off the floor, 30 cm (1ft.) away from the walls and other stacks, and no more than 2.5 m (8ft.) high.
- Arrange cartons with arrows pointing up and with identification labels, expiry dates and manufacturing dates clearly visible.
- Store health commodities to facilitate "earliest-expiry, first-out" (EEFO) procedures and stock management.
- Store health commodities away from chemicals, flammable products and hazardous materials.
- Separate damaged and expired health commodities from usable commodities.
- Keep narcotics and other controlled substances in a locked place.
- Store flammable products separately with appropriate safety precautions.

Adapted from: *Guidelines for the Storage of Essential Medicines and Other Health Commodities, March 2006 revision* (John Sow Inc./DELIVER, 2004).

2.3 Estimating storage requirements

In order to effectively manage stock and minimize the risk of loss you, as mid-level manager, must:

1) determine the volume the vaccines and safe-injection equipment occupy;
2) determine how much cold-chain and dry-storage capacity is available;
3) know how to manage cold-chain and dry-storage space effectively.

Box 1.4: What is "volume per dose" and is it important?

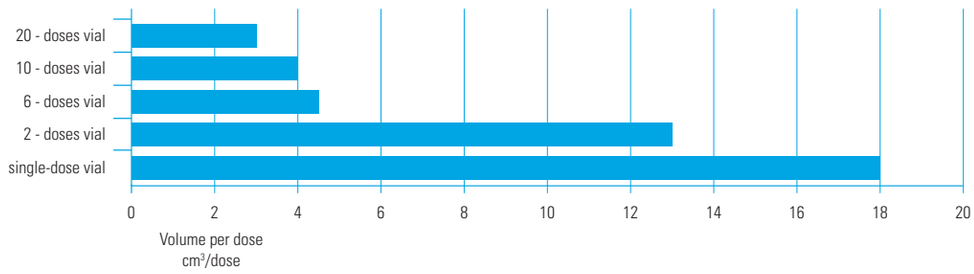
Each type of vaccine and syringe has different packaging. You need to know the size of these packages to estimate storage requirements.

Volume per dose refers to the volume occupied by each dose of vaccine, including its secondary packaging.

Figure 1.4 below shows different HepB vial sizes and the volume per dose required for each. Using the incorrect volume per dose in your calculations could have a serious impact on your vaccine storage requirements.

For more information, refer to the *Guidelines on the international packaging and shipping of vaccines* (WHO/IVB/05.23).

Figure 1.4: Volume per dose required for different HepB vaccine presentations



2.3.1 Estimating the total volume required to store vaccines

It is essential to estimate the total storage volume required for vaccines in order to determine whether cold-chain storage capacity is sufficient. Table 1.9 below shows the method used to calculate the storage volume needed per quarter in Omboby province for a target population of 100 000 infants and pregnant women.

Table 1.9: Estimating total storage volume required for vaccines, Omboby province, target population 100 000 (infants and pregnant women)

Vaccines	Packaging doses per vial	United packed volume (cm^3)	Annual vaccine doses needed	Quarterly vaccine doses needed	Total storage volume (cm^3)	Total storage volume (litres)	Storage volume according to temperature ranges (litres)	
							-15 °C to -25 °C	+2 °C to +8 °C
A	B	C	D	E=D/4	F=C*E	G=F/1000	H	I
OPV (oral)	20	1.0	532 000	133 000	133 000	133	133	
TT	20	2.0	266 000	66 500	133 000	133		133
BCG	20	1.2	200 000	50 000	60 000	60		60
Measles	10	3.5	133 000	33 250	116 375	116		116
Hib	2	6.0	315 000	78 750	472 500	473		473
DTP-HepB	2	6.0	315 000	78 750	472 500	473		473
Total					**1 387 375**	**1 388**	**133**	**1 255**
DTP-HepB-Hib	1	12.9	315 000	78 750	1 015 875	1 016		1 016
Total					**1 458 250**	**1 458**	**133**	**1 325**

Two different formulations of pentavalent vaccine are considered above:

a) DTP-HepB+Hib in a **two-dose formulation**, where the freeze-dried Hib component is reconstituted with the liquid DTP-HepB using a 2 ml reconstitution syringe;

b) DTP-HepB-Hib in a **single-dose** liquid formulation which requires no reconstitution syringe.

From these net calculations, you can see that Omboby province will require at least 133 litres of freezing capacity and more than 1254 litres of refrigeration capacity to store DTP-HepB + Hib and routine vaccines for 3 months.

Complete Table 1.9 as outlined below.

Column A: Include all vaccines currently in the schedule.

Column B: For each vaccine include the number of doses per vial according to the presentation being used.

Column C: List the unit packed volume for each vaccine **(that is, the volume occupied by each dose or syringe, including packaging)**. In the absence of known packaged volume, measure the length, width and height of the packaging to calculate the volume, then divide it by the number of doses per vial.

Columns D and E: Document the expected vaccine doses to be stored annually (column D) and quarterly (column E) for each vaccine presentation. Refer to Table 1.1 for details on how to calculate these quantities.

Column F: Calculate the total storage volume of vaccines by multiplying the unit packed volume (Column C) by the expected quarterly vaccine doses (column E).

Column G: Convert the total storage volume from cubic centimetres to litres by dividing by 1000.

Column H, I: Distribute the volume to be stored according to the appropriate temperature range for each vaccine and diluent.

Bottom row: Add the volumes needed for each temperature category to get the total storage volume required for each.

Assumption 1: Supplies are received in Omboby province every quarter (every three months).

Assumption 2: The target population of Omboby province is 100 000 infants and pregnant women.

Assumption 3: Diluents will not be refrigerated at the provincial level; rather, this will be undertaken at the district or health-facility level prior to each immunization session.

Assumption 4: Only routine immunization services will be offered during a quarter – that is, no supplemental immunization activities are planned in Omboby province for the period in question.

Assumption 5: Unit packed volume refers to the volume of each dose of vaccine including packaging. The mid-level manager will need to adjust this according to the specific vaccine types in his/her country.

Assumption 6: The mid-level manager will need to perform additional calculations (not shown here) to estimate the number of ice packs required and the refrigerator space needed to freeze them.

Assumption 7: All other requirements, such as diluents, safety boxes and syringes, have been ordered in a manner consistent with the national bundling policy.

2.3.2 Estimating the total volume required to store safe-injection equipment

Implementing a bundling policy (see Section 3.1) requires that adequate safe-injection equipment be made available to administer the vaccines. The safe-injection equipment, stored at ambient temperatures in dry storage, can occupy a large volume. Adequate storage space must therefore be estimated and allocated for these items.

In the previous example we estimated the total storage volume required for a quarterly delivery of vaccines to Omboby province. Now we will estimate the total capacity required in Omboby province to store the safe-injection equipment that will be bundled with those vaccines.

Table 1.10: Estimating total storage volume required for safe-injection equipment, Omboby province

Safe-injection equipment, diluents & other supplies	Unit packed volume (cm³)	Expected quarterly quantity needed (units)	Total storage volume (cm³)
A	B	C	D=(B*C)/1 000 000
0.05 ml AD syringes (only used for BCG)	35.9	27 750	1.00
0.5 ml AD syringes	60.6	165 000	10.00
2 ml reconstitution syringes	34.3	41 875	1.44
5 ml reconstitution syringes (only used for measles)	57.2	3 325	0.19
Safety Boxes (5 litres)	800.0	2 395	1.92
Sub total syringes	988.0	240 345	**14.54**
for BCG	0.7	50 000	0.04
for measles	4.0	33 250	0.13
SubTotal diluents	4.7	83 250	0.17
Droppers for OPV (20 dose vial)	0.9	133 000	0.12
Grand Total			**14.82**

As with the previous tables, the calculation above applies if Omboby province is using freeze-dried DTP-HepB+Hib vaccine; the details below apply if the province is using liquid DTP-HepB-Hib vaccine.

Sub total syringes	988.0	200 576	**12.87**
Grand Total			**13.16**

From these calculations you can see that, to store safe-injection equipment for 3 months, Omboby province will require dry storage facilities of at least 14.82 cubic metres if DTP-HepB+Hib vaccine is used, or 13.16 cubic metres if the liquid DTP-HepB-Hib is used.

Complete Table 1.10 as described below.

Column A: List the safe-injection equipment, diluents and other supplies that are being used.

Column B: For each item list the unit packed volume (refer to the *WHO/UNICEF Product Information Sheets* [WHO/V&B/00.13] and to Annex 5).

Column C: Document the expected quarterly quantity needed for each equipment type (see Table 1.1 for annual requirements and divide by 4).

Column D: Multiply the unit packed volume in cubic centimetres (Column B) by the quantity needed (Column C), then divide by 1 000 000 to get the total storage volume in cubic metres.

Assumptions: The same assumptions apply as for Table 1.9.

2.4 Calculating existing storage capacity

2.4.1 Calculating the total volume available to store vaccines

Having estimated the **storage requirements** for vaccines and safe-injection equipment in Omboby province, we can calculate the total volume of existing **storage capacity** to ensure there is adequate cold-chain equipment to accommodate the vaccines. Information on using a cold/freezer room is not provided in this module; however, detailed information can be found in the *User's handbook for vaccine cold rooms and freezer rooms* (WHO/V&B/02.31).

Note that this method will allow for better forward planning; however, when ordering, countries should always have spare storage space (minimum 25%) to allow for more flexibility.

Table 1.11 provides an example of how to calculate the total capacity of available cold-chain equipment in Omboby province.

Table 1.11: Calculating available cold-chain capacity, Omboby province

EQUIPMENT IDENTIFICATION			Code PIS / PQS or domestic	Net vaccine storage capacity (litres)		No. of equipments available	Total net vaccine storage capacity (litres)	
Type	Make	Model		-15 °C to -25 °C	+2 °C to +8 °C		-15 °C to -25 °C	+2 °C to +8 °C
A	B	C	D	E	F	G	H=E*G	I=F*G
Ice-lined refrigerator	Electrolux	TCW 1152/CF	E3/24-M		169	4		676
Vaccine/ice-pack freezer	Vestfrost	MF 314	E3/98-M	264		2	528	
Ice-lined refrigerator	Vestfrost	MK 304	E3/82-M		108	3		324
Ice-lined refrigerator	Vestfrost	MK 204	E3/81-M		63	1		63
Total						**10**	**528**	**1063**

From these calculations, you can see that Omboby province has a total freezer capacity of 528 litres and refrigerator capacity of 1063 litres, spread over 10 pieces of equipment.

Complete Table 1.11 as described below.

Columns A–D: List the types of cold-chain equipment available and provide the equipment specifications (refer to the WHO/UNICEF *Product Information Sheets* [WHO/V&B/00.13] or manufacturers' data).

Columns E, F: Insert the vaccine storage capacity of each piece of cold-chain equipment according to the two temperature ranges (again refer to *the WHO/UNICEF Product Information Sheets* [WHO/V&B/00.13] or manufacturers' data).

Column G: Specify the number of pieces of equipment of each type available.

Column H: Calculate the total net vaccine freezer capacity by multiplying the vaccine storage capacity (column E) by the number of pieces of equipment of that type available (column G).

Column I: Calculate the total net vaccine refrigerator capacity by multiplying the vaccine storage capacity (column F) by the number of pieces of equipment of that type available (column G).

Columns G–I, bottom row: Add the volumes available for each temperature category to get the total vaccine-storage volume.

Assumption 1: *The mid-level manager will need to perform additional calculations (not shown here) to estimate the number of ice packs required and the refrigerator space needed to freeze them.*

Box 1.5: Will I have a shortage of cold-chain capacity?

It is easy to determine whether you will experience a shortage of cold-chain capacity once you have:

a) estimated the total volume required to store vaccines (see para. 2.3.1);

b) calculated the total volume available to store vaccines (see para. 2.4.1).

Then calculate the difference: B (the available capacity) minus A (the required capacity).

Type of storage	Required capacity in litres (A)	Available capacity in litres (B)	Shortage?	
			Yes	No
-15 °C to -25 °C				
+2 °C to +8 °C				

The balance will show whether you will experience a shortage of cold-chain capacity unless action is taken to address the problem.

Learning activity 1.2: Analysis and problem solving cold-chain space

You are an EPI manager in Pokhara province with a target population of 100 000 infants and pregnant women.

You must determine whether there is sufficient space to receive a shipment of vaccines that is on its way to your store. Note that the new shipment will include pentavalent vaccine (DTP-HepB-Hib) which will ultimately replace DTP nationwide. The pentavalent vaccine is presented in a single-dose vial containing all five antigens in liquid form.

The following information is available:

Vaccines information		Vaccines currently in stock	Expected new shipment
Vaccines	**Dose per vial**	**Doses**	**Doses**
BCG	20	15 000 doses	50 000 doses
DTP	10	10 000 doses – remaining after decision to introduce the pentavalent vaccine	-
OPV	10	35 000 doses	130 000 doses
OPV	20	120 000 doses for polio SIA	-
Measles	10	10 000 doses	30 000 doses
YF	10	5000 doses	35 000 doses
TT	20	-	200 000 doses – including 120 000 for TT campaign to be conducted in 3 months
Pentavalent (DTP-HepB-Hib)	1	-	100 000 doses – to start introduction

TASK 1: Complete the following table to estimate the total storage volume required for all vaccines in Pokhara province – that is, vaccines that are *currently* in stock and also the *expected* new shipment.

Estimating the total storage volume required for vaccines, Pokhara province

	Vaccines	Packaging doses per vial	Unit packed volume (cm^3)	Current vaccine doses	Expected vaccine doses	Total storage volume (cm^3)	Total storage volume (litres)	Storage volume according to temperature ranges (litres)	
								-15 °C to -25 °C	+2 °C to +8 °C
	A	B	C	D	E	F=(C*D)+(C*E)	G=F/1000	H	I
Vaccines	OPV (oral)	20	1.0						
	OPV (oral)	10	2.0						
	TT	20	2.0						
	BCG	20	1.2						
	Measles	10	3.5						
	DTP	10	3.0						
	YF	10	2.5						
	DTP-HepB-Hib	1	12.9						
	Total								

The following table shows the available cold-chain capacity in Pokhara province.

Available cold-chain capacity, Pokhara province

EQUIPMENT IDENTIFICATION			Code PIS / PQS or domestic	Net vaccine storage capacity (litres)		No. of equipments available	Total net vaccine storage capacity (litres)	
Type	Make	Model		-15 °C to -25 °C	+2 °C to +8 °C		-15 °C to -25 °C	+2 °C to +8 °C
A	B	C	D	E	F	G	H=E*G	I=F*G
Ice-lined refrigerator	Electrolux	TCW 1152/CF	E3/24-M		169	4		676
Vaccine/ice-pack freezer	Vestfrost	MF 314	E3/98-M	264		2	528	
Ice-lined refrigerator	Vestfrost	MK 304	E3/82-M		108	3		324
Ice-lined refrigerator	Vestfrost	MK 204	E3/81-M		63	1		63
Total						**10**	**528**	**1063**

TASK 2: Complete the following table to determine whether Pokhara province will have a shortage of cold-chain capacity (subtract the required capacity from the available capacity to get the balance).

Estimated cold-chain shortage

Type of storage	Required capacity in litres (A)	Available capacity in litres (B)	Shortage ?	
			Yes	No
-15 °C to -25 °C				
+2 °C to +8 °C				

TASK 3: As the mid-level manager for Pokhara province, propose three actions that you can take to address the shortage of storage space. Highlight the implications of taking each of these actions.

Options to address shortage of cold-chain space

	Proposed action to take	Implication of action
1.		
2.		
3.		

2.4.2 Calculating the total volume available to store safe-injection equipment

To calculate the total volume of storage available for safe-injection equipment, you can follow the same principles as those used for calculating cold-chain capacity.

a) Identify the different storage locations to be used.

b) Determine the total volume in cubic metres available at each location.

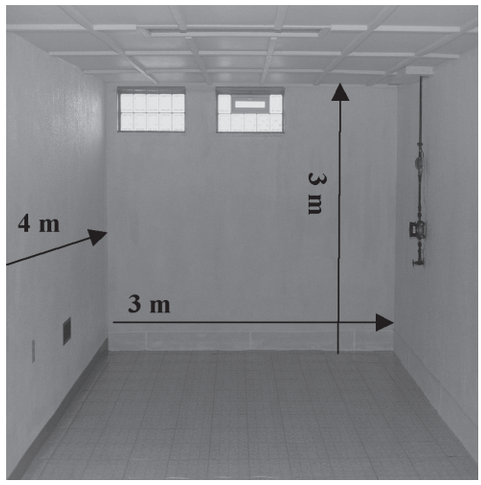
c) Estimate how much of the total volume is **occupied** by existing equipment, and subtract this from the available volume.

From this information you will know whether you will be able to accommodate your new delivery of safe-injection equipment.

Learning activity 1.3: Applying storage layout principles to a safe-injection equipment storeroom

You are the mid-level manager in Tillte province and are expecting the usual quarterly delivery of safe-injection equipment for your province. It will include AD syringes, reconstitution syringes, safety boxes and vaccine diluent (which does not need to be refrigerated). This is a total volume of 17 cubic metres. The dimensions of your storeroom are 3 metres wide by 4 metres long by 3 metres high, as shown in the figure below. Your existing safe-injection equipment already occupies 3 cubic metres in the storeroom.

Dimensions of safe-injection equipment storeroom, Tillte province



TASK 1: How will you organize the storeroom so that a) the existing safe-injection equipment can be accessed and issued first, and b) the incoming supplies can be stacked so that each category of goods received can be accessed easily?

2.5 Adapting to changing cold-chain storage needs

2.5.1 Adapting to changing vaccine storage needs at the provincial level

As mid-level manager you may be required to revise storage needs from time to time. This will arise when:

a) a new vaccine arrives and additional storage space is required; and/or

b) old equipment needs to be replaced.

In the previous section we dealt with calculating cold-chain space needed; in this section we will give an example of how vaccine storage space needs to be recalculated if a new vaccine is introduced.

Let us suppose the vaccine schedule in a province is changing from DTP to DTP-HepB-Hib vaccine.

Table 1.12 shows the current storage space needs. Table 1.13 shows the future storage needed when the new vaccine is introduced.

Table 1.12: Example showing storage space needed for a province with a target population of 40 000 using DTP vaccine (10-dose vials)

Vaccines	Target population	Number of doses	WMF	Annual doses needed	Packed volume per dose (cm^3)	Total volume (cm^3)	Total volume (Litres)	Quarterly volume (Litres)	# ILR needed (108 L)		# Gas or Kero needed (55 L)
A	B	C	D	E=B*C*D	F	G=E*F	H=G/1000	I=H/4	J=I/108		K=I/55
OPV (oral)	40 000	4	1.33	212 800	1.0	212 800	213	53			
TT	40 000	2	1.33	106 400	2.0	212 800	213	53		**OR**	
BCG	40 000	1	2.00	80 000	1.2	96 000	96	24			
Measles	40 000	1	1.33	53 200	3.5	186 200	186	47			
DTP	40 000	3	1.33	159 600	3.0	478 800	479	120			
Total						**1 186 600**	**1 187**	**297**	**3**		**6**

Table 1.13: Example showing storage space needed for the same province with a new schedule using DTP-HepB-Hib vaccine (single-dose vials)

Vaccines	Target population	Number of doses	WMF	Annual doses needed	Packed volume per dose (cm^3)	Total volume (cm^3)	Total volume (Litres)	Quarterly volume (Litres)	# ILR needed (108 L)		# Gas or Kero needed (55 L)
A	B	C	D	E=B*C*D	F	G=E*F	H=G/1000	I=H/4	J=I/108		K=I/55
OPV (oral)	40 000	4	1.33	212 800	1.0	212 800	213	53			
TT	40 000	2	1.33	106 400	2.0	212 800	213	53		**OR**	
BCG	40 000	1	2.00	80 000	1.2	96 000	96	24			
Measles	40 000	1	1.33	53 200	3.5	186 200	186	47			
DTP-HepB-Hib	40 000	3	1.05	126 000	12.9	1 625 400	1 625	406			
Total						**2 333 200**	**2 333**	**583**	**6**		**11**

By comparing Table 1.12 with Table 1.13 it is possible to calculate the additional storage space needed – in terms of both volume and refrigeration requirements.

In the example we assumed that ILRs, each with 108 litre capacity, were available. You will see that the provincial cold-storage space requirement increases from 3 ILRs to 6 ILRs to hold the expected quarterly supplies. If only 55-litre gas or kerosene refrigerators were available, the requirements would increase from 6 to 11 refrigerators.

Note that this method will allow for better forward planning; however, when ordering countries should always have spare storage space (minimum 25%) to allow for more flexibility, i.e. in this case, 1 more ILR or 2 more 55-litre gas or kerosene refrigerators.

2.5.2 Adapting to changing vaccine storage needs at the district level

The same method can be used at the district or health-facility level to determine whether storage requirements will change. It is important to calculate this because, as mid-level manager, you may be responsible for finding additional refrigeration space.

Sometimes, however, the existing refrigeration equipment may be adequate to accommodate the change.

Learning activity 1.4: Estimating cold-chain equipment needs for introducing a new vaccine

You are the mid-level manager in Porrit province and are preparing for the introduction of a new vaccine in your province.

TASK 1: Calculate the present refrigeration needs for one of the districts by completing the table below. The vaccine schedule is set but you will need to decide on the target population.

Vaccines	Target population	Number of doses	WMF	Annual doses needed	Packed volume per dose (cm^3)	Total volume (cm^3)	Total volume (Litres)	Quarterly volume (Litres)	# ILR needed (108 L)
A	B	C	D	E=B*C*D	F	G=E*F	H=G/1000	I=H/4	J=I/108
OPV (oral)		4	1.33						
TT		2	1.33						
BCG		1	2.00						
Measles		1	1.33						
DTP		3	1.33						
Total									

TASK 2: Add a new vaccine to the schedule and recalculate the refrigeration requirements based on the new schedule. What difference does the new vaccine make to refrigeration requirements at the district level?

Vaccines	Target population	Number of doses	WMF	Annual doses needed	Packed volume per dose (cm^3)	Total volume (cm^3)	Total volume (Litres)	Quarterly volume (Litres)	# ILR needed (108 L)
A	B	C	D	E=B*C*D	F	G=E*F	H=G/1000	I=H/4	J=I/108
OPV (oral)		4	1.33						
TT		2	1.33						
BCG		1	2.00						
Measles		1	1.33						
DTP		3	1.33						
Total									

Notes :

3. Distribution and transport

Distribution systems for vaccines and safe-injection equipment aim to ensure continuous availability of adequate quantities of potent vaccine and safe-injection equipment. A mid-level manager should aim to have a well-functioning distribution system and clearly establish:

a) the supply period for each level and the corresponding quantities of vaccines and safe-injection equipment to be supplied, and

b) the suitable route and transport needed to distribute the vaccines and safe-injection equipment.

3.1 Bundling AD syringes with vaccines

AD syringes have built-in self-disable mechanisms that ensure single use. AD syringes are the preferred equipment for all types of immunization sessions. In 2003 a joint WHO-UNICEF-UNFPA statement was issued, calling for the exclusive use of AD syringes in immunization programmes *(WHO-UNICEF-UNFPA Joint statement on the use of auto-disable syringes in immunization services.* Geneva, World Health Organization, [WHO/V&B/99.25]).

The *bundling* concept (see Box 1.6) was developed to ensure that AD syringes, along with other necessary vaccine safety equipment, are available at the point of use, thereby promoting safe-injection practice. Bundling is considered *best practice*. However, since it involves distributing AD syringes, reconstitution syringes and safety boxes with the appropriate quantities of vaccines and diluents, the mid-level manager needs to take the points outlined below into consideration, prior to implementing a bundling policy.

a) If vaccines, AD syringes, reconstitution syringes and safety boxes are handled by different departments, close communication and coordination must be ensured so that the correct quantities of vaccines and injection safety equipment are procured and distributed.

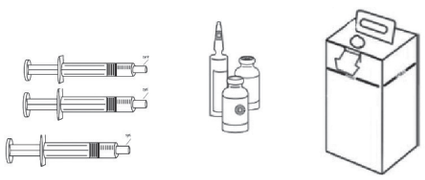
b) AD syringes and vaccines have different wastage levels. The acceptable wastage level for AD syringes is 10%, while for vaccines it varies from 5% to 50% depending on the antigen and vial size. Therefore, the unequal number of doses of vaccine and the number of AD syringes may be distributed along the supply chain. However, at point of use ensure that equal number of vaccine doses and AD syringes are placed in the vaccine carrier and carried to the outreach site.

c) At the point of use the supply of vials, AD syringes, diluent, and reconstitution syringes must be matched to the expected workload of each session. This is especially important for outreach service delivery.

Box 1.6: What is bundling?

The term "bundling" has been chosen to define the concept of a theoretical bundle which must comprise each of the following items:

- good quality vaccines,
- auto-disable syringes,
- safety boxes.



The implication is that none of the component items can be considered alone; each item must be considered as part of a "bundle" which contains the other two. "Bundling" has no physical connotation and does not imply that items must be "packaged" together.

Source: *WHO-UNICEF-UNFPA Joint statement on the use of auto-disable syringes in immunization services*. Geneva, World Health Organization, 1999 (WHO/V&B/99.25).

3.1.1 Putting the bundling policy into practice

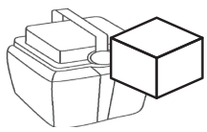
Imagine you are the mid-level manager in Mulu province. You are preparing to requisition an order for BCG vaccine from the national level for the target group of 100 000 infants in your province. Based on 50% wastage (or WMF = 2) you calculate that 200 000 doses are required for a year.

Since Mulu province has just implemented a bundling policy, you also need to order the corresponding number of AD syringes; you calculate this to be 111 000 syringes based on 10% wastage (or WMF = 1.11).

Table 1.14: An example of the bundling concept

Supply-chain level	Target population (infants)	BCG vaccine, doses required	AD syringes, units required
Province	100 000	200 000	111 000
District	30 000	60 000	33 000
Health facility	10 000	20 000	11 000

At point of use (Outreach Site)



BCG 2 vials (40 doses) and 2 vials of diluents
40 AD syringes
2 reconstitution syringes

The system of using a WMF for vaccines that is different to the WMF for syringes continues through the supply chain. At the point of use, especially for outreach, ensure that you carry equal number of vaccine doses and injection equipment (unused doses of vaccines may not be returned after the session, but unused syringes can be).

Note 1: Bundling policies should cover AD syringes, safety boxes and reconstitution syringes.

Learning activity 1.5: Reviewing the bundling policy in your country

TASK 1: In your country what is the system for ordering, supplying and distributing AD syringes, reconstitution syringes and safety boxes?

TASK 2: Is there more than one department responsible for supplying vaccines and safe-injection equipment? If yes, how do they coordinate distribution?

TASK 3: If there have been stock-outs of AD syringes, reconstitution syringes and/or safety boxes, what have been the causes?

3.2 Preparing a distribution plan for vaccines and safe-injection equipment

Several steps need to be taken to ensure that vaccines and safe-injection equipment are delivered to the peripheral levels in the correct quantities, on time and under the correct transportation conditions.

Firstly, the frequency of supply is usually determined at the national level, based on national guidelines and standard operating procedures. In most countries, a supply period of three months is established for the first and second administrative levels with more frequent deliveries at the peripheral levels (see Table 1.2).

Managers at national and provincial levels then need to develop a comprehensive distribution plan for the provinces and districts. Each province must establish a list of districts and estimate the monthly or quarterly quantities of vaccines and safe-injection equipment to be supplied.

Having calculated the packed volumes of vaccines and safe-injection equipment, the manager can then calculate *for each district*:

a) the total volume of vaccines to be distributed and the number of cold boxes needed for transport;

b) the total volume (in cubic meters) of safe-injection supplies to be bundled with vaccines.

A form is provided in Annex 7 to help calculate the transportation needs. This form is based upon target population and monthly supply period.

3.2.1 Estimating transportation needs

Once you have calculated the quantity of supplies to be distributed to each district, and their volume, you can then calculate the number of cold boxes needed and the best method of transportation.

Example: You are arranging the transportation of vaccines and safe-injection equipment to district Indus with a total population of 30 000. Using the form in Annex 7, the total volume for vaccines is calculated as 167 litres and for safe-injection equipment (including diluents) it is 1.6 cubic metres. Vaccines are usually transported in 20-litre cold boxes so, for this delivery, you will need 9 cold boxes.

3.2.2 Vehicle capacity to carry vaccines and safe-injection equipment

The choice of vehicle for supplying the districts will depend on many factors in addition to the quantity of vaccines and safe-injection equipment. Things to consider include the condition of the roads, the number of other people that need transportation, the distance to be travelled and the availability of services such as fuel supply.

Table 1.15 describes the range and capacity of vehicles typically used for supply and distribution of vaccines.

The proper way to condition frozen ice packs in preparation for distribution of vaccines is explained in Box 1.7. Alternatively, under most weather conditions, cool-water packs can be appropriately used to transport vaccines.

Box 1.7: What do I need to know about conditioning ice packs?

The proper use of ice packs is essential for maintaining the potency of vaccines. You will need to be well organized to make sure you have enough ice packs available, especially in times of high need such as during supplementary immunization activities.

You need to "condition" ice packs to prevent them from freezing freeze-sensitive vaccines during transport.

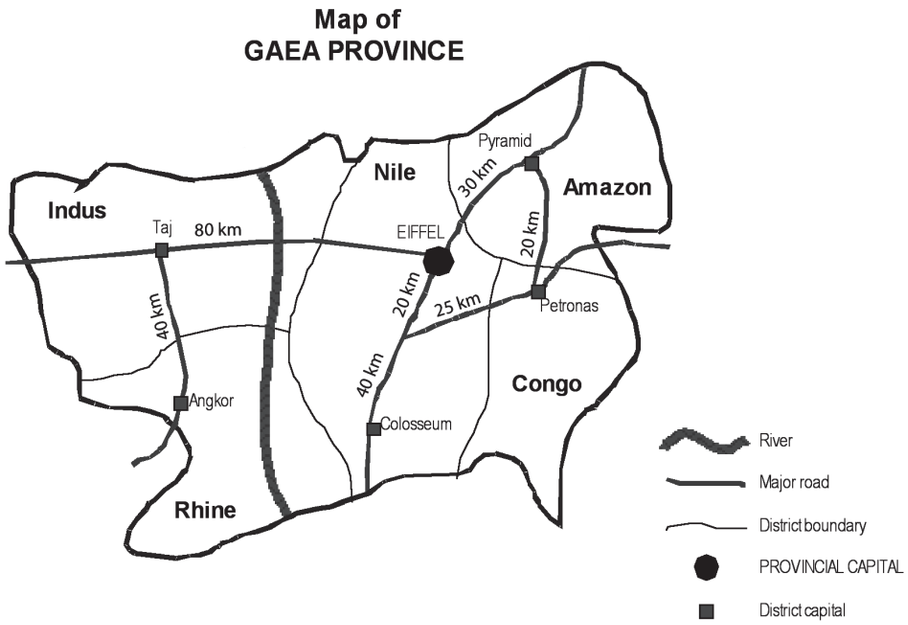
To condition an ice pack, remove it from the freezer compartment and keep it at room temperature until the ice within it melts. When you shake the ice pack and can hear the water inside, it is ready to be loaded into the cold box or vaccine carrier. The time this takes varies depending on the ambient temperature; it can take over 30 minutes.

Table 1.15: Transport vehicle capacity to carry vaccines and safe-injection equipment

Type of vehicle	Capacity to carry		Travelling range in 1 day	Comments
	People	Load		
Small sized truck (single cab) or pickup	Driver + 2	4.5 m^3 (stacked to 1 m height)	200 km	Carrying capacity is adequate for 8 cold boxes (20 litres) and 1.9 m^3 of safe-injection equipment.
4-wheel drive pickup (double cab)	Driver + 4	2.74 m^3 (stacked to 1 m height)	200 km	Carrying capacity is adequate for 6 cold boxes (20 litres) and 1.2 m^3 of safe-injection equipment.
4-wheel drive (regular, closed back)	Driver + 4	1.8 m^3	200 km	Carrying capacity is adequate for 3 cold boxes (20 litres) and 0.6 m^3 of safe-injection equipment.
Motorcycle	Rider	One 20 litre cold box (0.2 m^3) on the rear carrier and 40 litres (0.04 m^3) in 2 carrier bags	50 km	Capacity adequate for a health facility but not a district.
Bicycle	Rider	20 litre cold box (0.2 m^3) and 1 saddle bag (0.02 m^3)	10 km	Adequate for outreach service delivery.
Outreach vaccinator	0	1 vaccine carrier and 1 backpack (0.02 m^3)	5 km	

Learning activity 1.6: Vaccines and safe-injection equipment distribution plan

You are a mid-level manager in Gaea province and are responsible for arranging the delivery of vaccines and safe-injection equipment from the provincial capital, Eiffel, to the districts. There are vaccine storage points at each of the five district capitals; the province has a medium-sized single-cab truck that is used for the purpose.



The present monthly requirements for each district are listed below.
*External dimensions of 20-litre cold box: 71x 55x 50 cm = approx. 0.2 m^3.

District name	Target population	Total volume of vaccines to be distributed (monthly)	Number of cold boxes (20 litres)*	Total volume of safe-injection equipment in m^3 (AD syringes 0.5 ml, 0.05 ml; reconstitution syringes 2 ml, 5 ml; safety boxes and diluents)
Indus	30 000	160	8	1.9
Rhine	15 000	80	4	0.9
Nile	20 000	107	6	1.2
Congo	25 000	134	7	1.6
Amazon	10 000	53	3	0.6

TASK 1: Complete the table below to draw up a plan to distribute the vaccines and safe-injection equipment to all five districts of the province.

Route	Frequency of delivery	Days needed to cover the entire province

In the next few months the immunization schedule in your country will change with the introduction of liquid pentavalent vaccine (DTP-HepB-Hib) in a single-dose vial. You have calculated the new monthly distribution requirements for Indus district (see Annex 7) and see that the needs will change.

TASK 2: Identify the problems that you will now face in Indus district with regard to transport, distribution and the cold chain.

3.3 Collection of waste

Vehicles that deliver vaccines and safe-injection equipment can also be used to carry waste back to where it can be safely destroyed. For example, a truck with a load capacity of 2 cubic metres can take a load of approximately 30 full safety boxes to where they can be safely disposed of. This subject is dealt with in more detail in another module in this series *(Module 3: Immunization safety)*.

Notes :

4. Monitoring and supervision

An integral part of the overall EPI management system is the monitoring of immunization supplies. Routine monitoring of immunization activities and supplies takes place monthly. Data on the availability of supplies and their utilization are regularly collected to monitor the efficiency of the cold chain and vaccine management systems.

Monitoring vaccines and safe-injection equipment:

- ensures the availability of adequate quantities and the assured quality of each item;
- ensures appropriate use in service delivery;
- enables the timely detection of management problems in the implementation of immunization activities so that corrective action can be taken;
- guides the planning process.

4.1 Indicators to monitor vaccine and safe-injection supplies

Table 1.16 shows the main indicators used to monitor vaccines and safe-injection supplies. All these indicators can be measured from the data received on monthly stock levels – for example, the monthly reports from all the districts are consolidated into a database at the provincial level; it is then possible to track all the indicators for those districts from the database.

Table 1.16: Main indicators to monitor vaccine and safe-injection supplies

Indicators	Purpose
Availability of immunization supplies. Availability at any time (expressed in months) = current stock level in doses / monthly needs in doses	Gives information at any time on whether sufficient supplies are available to meet planned needs at that time, and assists with forward planning of supplies and distribution.
Bundling of vaccines and safe-injection equipment for distribution. No. of syringes or other supply available / no. of doses available Should be in the range of 0.5 to 1.0	Ensures that adequate supplies of vaccine and safe-injection equipment are available at any time.
Quality of vaccine storage. Number of refrigerators that were out of service for more than a day during a month / Total number of refrigerators	Ensures functional cold-chain equipment
Vaccine wastage at the service-delivery level.	a) Monitors service-delivery quality (wastage in opened vials). b) Monitors cold-chain quality (wastage in unopened vials).

4.2 Stock management

Monitoring stock levels will help you, as mid-level manager, to order adequate monthly or quarterly supplies and to make the shipment of supplies to peripheral levels on a timely basis.

Table 1.17 provides an example of a stock-management record, organized by type of vaccine or safe-injection equipment. This table design enables you to monitor stock against minimum and maximum stock levels.

Regularly update the stock-management record by physically counting the stock and adjusting the record as needed.

Table 1.17: Sample form used for stock management

Vaccines or safe-injection equipment name	Minimum stock	Quarterly supply	Maximum stock (minimum + quarterly supply)

Date	Received from or Issued to	Number of vials/units		Presentation (doses/vial or units/box)	Total # doses or units	Batch #	Expiry date	Status of VVM	Total balance (doses)/(units)	Comments
		Received	Issued							

4.3 Temperature monitoring

4.3.1 Monitoring the temperature in vaccine refrigerators

WHO advocates the use of new time-temperature devices for continuous temperature recording. Temperature monitoring is not a spot check; it is a continuous process and with the introduction of these new time-temperature devices, you will have full data, even for the weekends and holidays.

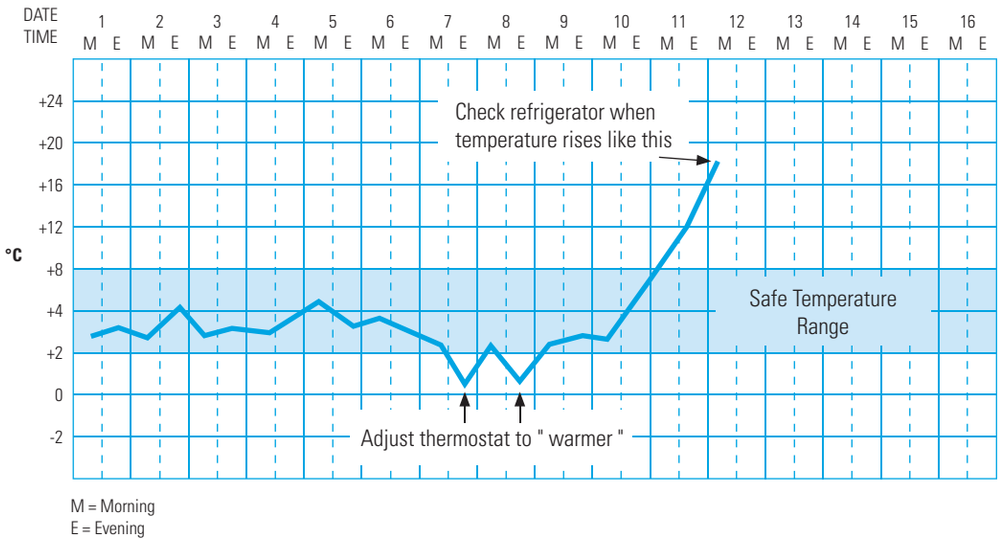
In the absence of such devices, to monitor the temperature of the main section of a refrigerator you need:

- a thermometer;
- a temperature chart that you tape to the outside of the refrigerator door.

To monitor the temperature, proceed as outlined below.

- Set the refrigerator thermostat during the coldest part of the day to around +2 °C to +4 °C. Once the thermostat has been set, monitor temperatures first thing in the morning and before you leave the post in the afternoon/ evening. If the temperature is between +2 °C and +8 °C, do not adjust the thermostat.
- Continue to monitor the temperature first thing in the morning and before you leave the post in the afternoon; this should be done every day.
- Record the time and temperature for the day on the refrigerator temperature chart, as shown below.

Figure 1.5: Refrigerator temperature chart



When a chart has been completed, replace it with a new one. Keep the completed charts in a record book for future reference. Take action when the temperature goes out of range.

4.4 Using the VVM to monitor the quality of vaccine vials

a) Under circumstances where vaccines could have been exposed to excessive heat during shipment or storage, the VVM will always indicate whether or not the vaccine is safe to use.

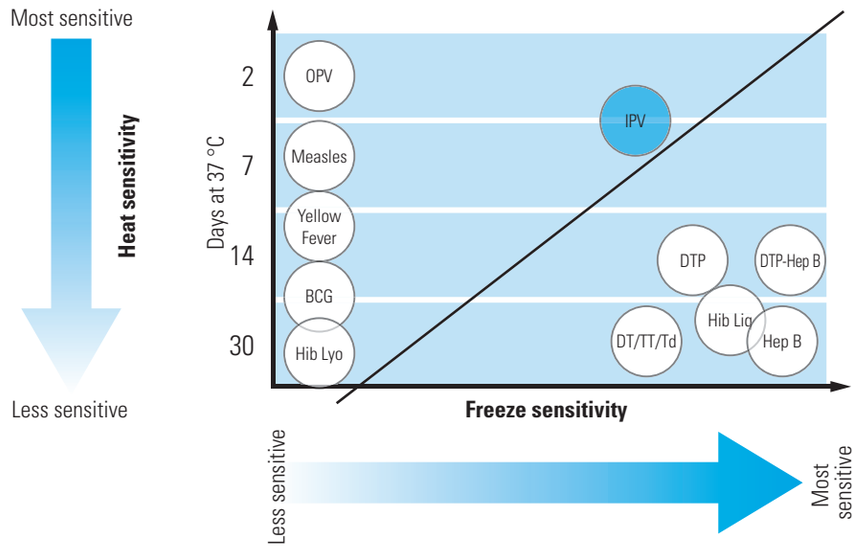
b) The VVM will only apply to the vaccine in the vial on which it appears. It cannot be used as a proxy for other vaccines; they may have different temperature sensitivities and storage history.

c) The VVM is a useful indicator when conducting outreach activities. Even under intermittent cold-chain conditions vaccines can continue to be used according to the VVM status. A VVM will not, however, indicate whether a freeze-sensitive vaccine has been frozen.

d) All health workers must know how to interpret a VVM (see Annex 4). Follow up on this with supervisory visits if necessary.

There are currently (at the time of writing) four types of VVM in use – types 2, 7, 14 and 30. Each number refers to the number of days the VVM takes to reach the discard point if it is kept at +37 ° C. The various types of VVMs are assigned to different vaccines according to their heat sensitivity – for example, a VVM type 2 is assigned to OPV which is a very heat-sensitive vaccine, while VVM type 14 is assigned to DTP-HepB which is much less heat sensitive.

Figure 1.6: The four different VVM types and their relationship to temperature sensitivity in EPI vaccines



4.5 Reducing vaccine wastage

Improving the use of vaccine supplies and avoiding unnecessary wastage often depends upon better management at all levels. However, even under the best management, some degree of vaccine wastage is expected in any immunization service. Wastage can occur at any stage. It can occur in the cold store at central level, at various intermediate levels, at the point of use at an immunization session and during transportation. The factors associated with vaccine wastage can be classified as unavoidable or avoidable.

4.5.1 Unavoidable vaccine wastage factors

The most important unavoidable wastage factors involve:

- reconstituted vaccines that have to be discarded at the end of a session.

4.5.2 Avoidable vaccine wastage factors

Factors that can be controlled by improving vaccine management include:

- poor stock management resulting in over-supply and vaccines reaching expiry before use;
- cold-chain failure that exposes vaccines to unacceptably high or unacceptably low temperatures;
- incorrect dosage, e.g. the administration of 3 drops of OPV instead of 2 drops or the injection of 0.6 ml of vaccine instead of 0.5 ml;
- failure to comply with the multi-dose vial policy;
- the loss, breakage or theft of vials.

For more details refer to *Monitoring vaccine wastage at country level*. (WHO/V&B/03.18. Rev.1).

4.5.3 Putting coverage before wastage

The health worker must take a sufficient number of vials to the outreach session and be prepared to open a new vial even if it is only for one child.

Never admonish a health worker for high vaccine wastage since it may lead to less vials being opened and fewer infants and women being immunized.

Key point: The opportunity to immunize is more valuable than a dose of vaccine. The goal is to immunize the maximum number of infants and pregnant women or women of childbearing age. Do not hesitate to open a new vial of vaccine – you may not have another opportunity to provide a dose to that child or woman.

4.6 Supervision

Problems associated with cold chain, vaccine and safe-injection equipment management are among the most common to be encountered at all levels of the immunization system. Fortunately, it is often possible to solve problems through on-site corrective action during supervisory visits. Even if a problem cannot be solved on the spot, it is very likely that a supervisor will need to authorize the action to be taken, e.g. repair, replacement, etc. All supervisory visits should be thorough and systematic – it is useful to have a checklist and the supervisors themselves must have a thorough knowledge of the practices and procedures. This module and Module 4 in this series contain much of the information needed to make a supervisory visit effective. The following activities provide an example of how to conduct a supervisory visit.

Learning activity 1.7: Problem-solving during supervision visits

Below is an example of a checklist from a supervisory visit. Some comments have been entered in the form of problems observed.

TASK 1: What corrective action can the supervisor take to solve the problems observed, both on-site during the visit and in the longer term? Include any additional items (related to cold chain, vaccine management) that you would like to check during supervisory visits.

	Question	Yes/ No	Comment (problems observed)	On-site corrective action	Longer term corrective action
1	Are the vaccines stacked properly inside the refrigerator?	No	HepB close to freezer		
2	Are there any expired vaccines inside the refrigerator?	No			
3	Are there any vaccines with a VVM reaching the discard point?	Yes			
4	Do the health workers know how to read and interpret the VVM?	Yes			
5	Does the staff member know WHEN to perform the shake test and can he/she correctly perform the shake test (Annex 3)?	No			
6	Are AD syringes used for every immunization?	Yes			
7	Is the injection technique appropriate?	Yes			
8	Are safety boxes used to discard AD syringes?	Yes			
9	Does the stock register show adequate vaccines and safe-injection equipment? Is the current stock between minimum and maximum levels?	No	AD syringes out of stock		
10	Are temperature monitoring charts being updated regularly?	No	Not used		

Annex 1: Key references

1. *Adopting global vaccine management policies for national use.* Geneva, World Health Organization, 2002 (WHO/V&B/02.32).
2. *Effective Vaccine Store Management Initiative,* Modules 1–4. Geneva, World Health Organization, 2004 (WHO/IVB/04.17; WHO/IVB/04.18; WHO/IVB/04.19; WHO/IVB/04.20).
3. *Ensuring the quality of vaccines at the country level.* Geneva, World Health Organization, 2002 (WHO/V&B/02.16).
4. *Equipment performance specifications and test procedures. E1: Cold rooms and freezer rooms.* Geneva, World Health Organization, 2002 (WHO/V&B/02.33).
5. *Getting started with vaccine vial monitors.* Geneva, World Health Organization, 2002 (WHO/V&B/02.35).
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8. *How to look after a cold room or freezer room: self-assessment tool.* Geneva, World Health Organization, 2002 (WHO/V&B/02.30).
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10. *Monitoring vaccine wastage at country level: Guidelines for programme managers.* Geneva, World Health Organization, 2003 (WHO/V&B/03.18. Rev.1).
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12. *Quality of the cold chain: WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services.* Geneva, World Health Organization, 1999 (WHO/V&B/99.18).
13. *Reference manual for health workers on injection safety.* Ministry of Health, Kenya, 2004. Available at http://www.technet21.org/pdf_file/KM3LogisticsMan.pdf
14. *Study protocol for temperature monitoring in the vaccine cold chain.* Geneva, World Health Organization, 2005 (WHO/IVB/05.01).
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18. *WHO policy statement: The use of opened multidose vials of vaccine in subsequent immunization sessions.* Geneva, World Health Organization, 2000 (WHO/V&B/00.09).
19. *WHO-UNICEF-UNFPA Joint statement on the use of auto-disable syringes in immunization services.* Geneva, World Health Organization, 1999 (WHO/V&B/99.25). Available at: http://www.who.int/vaccines-documents/DocsPDF99/www9948.pdf

Annex 2: Indicative wastage rates for vaccines

The **wastage multiplication factor** (WMF) is a function of a programme's vaccine wastage. It is used to calculate vaccine supply needs. The vaccine wastage rate can vary greatly according to many characteristics of the programme such as session sizes, session plans, presentation of the vial and supply management.

The following tables can assist in calculating the WMF. Each country should, however, revise the figures based on local circumstances.

NOTE: WMFs may change depending on the type of immunization activity being undertaken such as special immunization activities (SIAs) versus routine.

Indicative wastage rates

Although countries should be encouraged to monitor their own wastage levels, in the absence of local data the following wastage rates, based on the type of vaccine and the number of doses per vial, can be used to estimate vaccine needs.

	Single-dose vial	2–6 dose vial	10–20 dose vial
Lyophilized vaccines	5%	10%	50%
Liquid vaccines	5%	10%	25%

Conversion table – wastage rate to WMF

The indicative wastage rate can be converted to the WMF by using the following quick reference guide.

Wastage rate	5%	10%	15%	20%	25%	30%	35%	40%	45%	50%
WMF	1.05	1.11	1.18	1.25	1.33	1.43	1.54	1.67	1.82	2

Example: Using the tables above to calculate the WMF for lyophilized Hib vaccine in 2-dose vials, the indicative wastage rate is 10%. This converts to a WMF of 1.11. So, for every dose of lyophilized Hib, 1.11 doses must be ordered to compensate for the 10% wastage.

Annex 3: The shake test

8 The shake test

The "shake test" can help give an idea whether adsorbed vaccines (DTP, DT, Td, TT or hepatitis B) have been subjected to freezing temperatures likely to have damaged them. After freezing, the vaccine no longer has the appearance of an homogenous cloudy liquid, but tends to form flakes which settle at the bottom of the vial after shaking. **Sedimentation is faster in a vial which has been frozen than in a vial, from the same manufacturer, which has not been frozen.**

The test should be conducted for all boxes where freeze indicators are found to be activated or temperature recordings show negative temperatures.

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 from the same manufacturer. Freeze the vial until the contents are solid (at least 10 hours at -10°C) and then let it thaw. This vial is the **control sample**. Mark the vial clearly so that it is easily identifiable and will not be used by mistake.

2 Choose a test sample

Take a vial (s) of vaccine from the batch (es) 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 by placing the vials on a table and not moving them further.

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 has most probably **not been frozen** and can be used. If the sedimentation rate is similar, the vial 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 control and test vials upside down and observe sedimentation taking place in the neck of the vial.

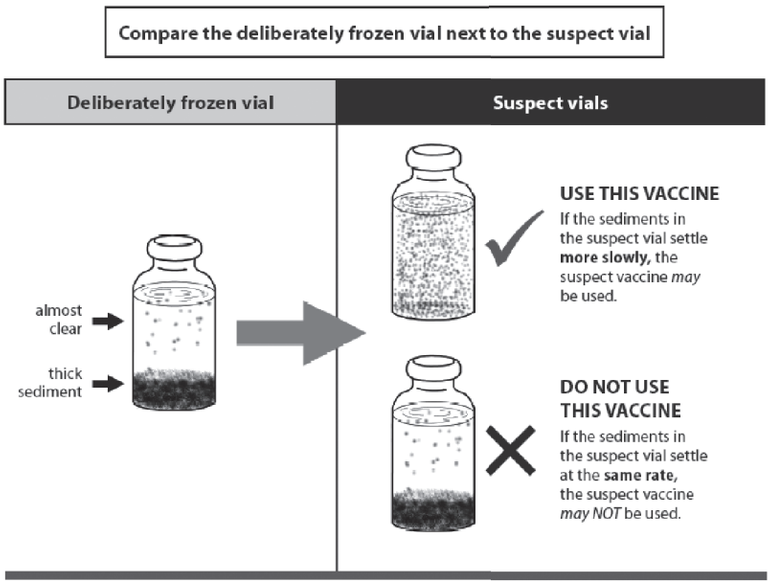
If the shake test procedure indicates that the test sample has been damaged by freezing, you should notify your supervisor immediately. Identify and separate all vaccines that may have been frozen and ensure that none are distributed or used.

Source: *Immunization in practice: A practical guide for health staff.* Geneva, World Health Organization, 2004.

Note:

Frozen samples can be used for shake tests only when testing the same vaccine from the same manufacturer and the same lot number. A new sample is needed for each manufacturer and lot number.

Figure 3R: The shake test

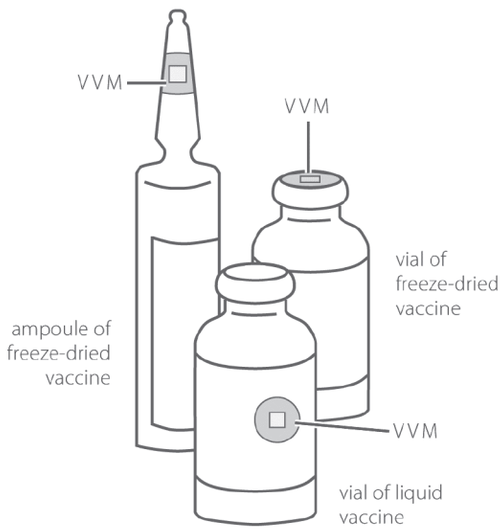


Annex 4 : Reading the VVM

A vaccine vial monitor (VVM) is a label on a vaccine vial ; it changes colour when the vial has been exposed to heat over a period of time. Before opening a vial, the status of the VVM must be checked to see whether the vaccine has been damaged by heat.

Most vaccines supplied through UNICEF today have a VVM attached. The VVM is printed on the vial label or cap. It looks like a square inside a circle. As the vaccine vial is exposed to more heat, the square becomes darker.

Figure 1.7 : VVM on vial label or cap



Only use a vial if the inner square of the VVM is lighter in colour than the outside circle. If any vial has a VVM where the inner square has begun to darken but is still lighter than the outer circle, it should be used before the vials with a lighter inner square.

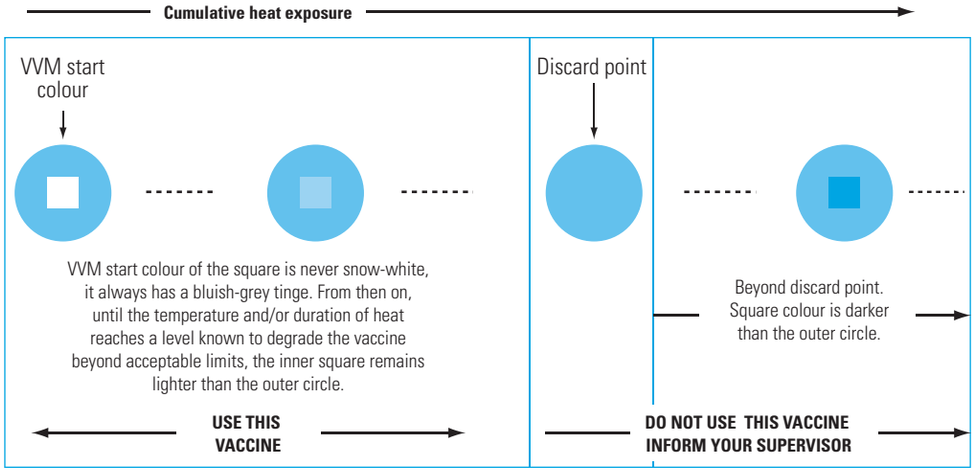
Important note :

VVMs do not measure exposure to freezing temperatures (for freeze-sensitive vaccines).

A VVM that is not at discard point does not exclude the possibility that the vaccine has been frozen. So, perform a shake test if freezing is suspected on freeze-sensitive vaccines with a good VVM.

Source : *Immunization in practice: A practical guide for health staff.* Geneva, World Health Organization, 2004.

Figure 1.8 : How to read a vaccine vial monitor (VVM)



Using the VVM to take vaccines outside the cold chain

Vaccines with VVMs can be taken out of the cold chain only if health workers and others handling the vaccines have been trained to interpret VVM readings correctly and if any vial bearing a VVM that has reached its end-point is discarded.

Managerially, however, it is wise to maintain vaccine in the cold chain for as long as possible during distribution. This ensures the maximum viable life in the field.

A policy permitting the use of vaccine outside the cold chain can be implemented either generally for all routine immunization activities or on a limited basis in certain areas or under special circumstances, such as :

- national immunization days ;
- reaching hard-to-reach geographical areas ;
- providing immunizations from house to house ;
- during cool seasons ;
- storage and transportation of freeze-sensitive vaccines (DTP, TT, DT, Td, hepatitis B and Hib vaccines) where the risk of freezing is greater than the risk of heat exposure.

Remember that freeze-dried vaccines (measles, BCG, yellow fever, and freeze-dried formulations of Hib) should not be transported to their point of use if the availability of ice cannot be guaranteed. Ice is necessary in order to keep the vaccines cool after they have been reconstituted.

For more details refer to the *WHO-UNICEF statement on vaccine vial monitors implementation : Marking the 10 years of successful implementation and role of vaccine vial monitors in reaching every child and mother* (WHO/IVB/07.04).

Annex 5 : Product information (vaccines and refrigerators)

Unit volumes for vaccines and diluents

VACCINES	Vaccine formulation	Mode of administration	Vaccine References initials	Number of doses per vial	Unit volume per dose (cm^3)	
					vaccines	diluents
BCG	lyophilized	ID	BCG	20	1.2	0.7
Diphtheria - Tetanus - Pertussis	liquid	IM	DTP	20	2.0	
Diphtheria - Tetanus - Pertussis	liquid	IM	DTP	10	3.0	
Diphtheria - Tetanus	liquid	IM	DT	10	2.0	
Tetanus - Diphtheria	liquid	IM	Td	10	3.0	
Tetanus - Toxoid	liquid	IM	TT	10	2.0	
Tetanus - Toxoid	liquid	IM	TT	20	3.0	
Tetanus - Toxoid - Uniject	liquid	IM	TT	1	25.0	
Measles	lyophilized	SC	Measles	1	9.3	20.0
Measles	lyophilized	SC	Measles	5	N/A	N/A
Measles	lyophilized	SC	Measles	10	3.5	4.0
Measles - Rubella freeze dried	lyophilized	SC	MR	10	2.5	4.0
Measles - Mumps - Rubella freeze dried	lyophilized	SC	MMR	1	16.0	20.0
Measles - Mumps - Rubella freeze dried	lyophilized	SC	MMR	10	3.0	4.0
Polio	liquid	Oral	OPV	10	2.0	
Polio	liquid	Oral	OPV	20	1.0	
Yellow fever	lyophilized	SC	YF	5	6.5	7.0
Yellow fever	lyophilized	SC	YF	10	2.5	6.0
Yellow fever	lyophilized	SC	YF	20	1.0	3.0
DTP - HepB combined	liquid	IM	DTP - HepB	1	9.7	
DTP - HepB combined	liquid	IM	DTP - HepB	2	6.0	
DTP - HepB combined	liquid	IM	DTP - HepB	10	3.0	
DTP - HepB + Hib to be combined	liquid	IM	DTP - HepB	1	32.0	
DTP - HepB + Hib to be combined	liquid	IM	DTP - HepB	3	24.0	
Hepatitis B	liquid	IM	HepB	1	18.0	
Hepatitis B	liquid	IM	HepB	2	13.0	
Hepatitis B	liquid	IM	HepB	6	4.5	
Hepatitis B	liquid	IM	HepB	10	4.0	
Hepatitis B	liquid	IM	HepB	20	3.0	
Hepatitis B Uniject	liquid	IM	HepB_Uniject	1	30.0	
Hib liquid	liquid	IM	Hib_liq	1	15.0	
Hib liquid	liquid	IM	Hib_liq	10	2.5	
Hib freeze - dried	lyophilized	IM	Hib_lyo	1	13.0	35.0
Hib freeze - dried	lyophilized	IM	Hib_lyo	2	6.0	
Hib freeze - dried	lyophilized	IM	Hib_lyo	10	2.5	3.0
DTP liquid + Hib freeze - dried	liquid + lyop.	IM	DTP + Hib	1	45.0	
DTP liquid + Hib freeze - dried	liquid + lyop.	IM	DTP + Hib	10	12.0	
DTP - Hib combined liquid	liquid	IM	DTP - Hib	1	32.3	
DTP - Hib combined liquid	liquid	IM	DTP - Hib	10	2.5	
DTP - HepB liquid + Hib freeze - dried	liquid + lyop	IM	DTP - HepB + Hib	1	22.0	
DTP - HepB liquid + Hib freeze - dried	liquid + lyop	IM	DTP - HepB + Hib	2	11.0	
DTP - HepB liquid + Hib freeze - dried	liquid + lyop	IM	DTP - HepB + Hib	10	5.3	
DTP - HepB - Hib liquid	liquid	IM	DTP - HepB + Hib	1	12.9	
Meningitis A/C	lyophilized	SC	MV_A/C	10	2.5	2.5
Meningitis A/C	lyophilized	SC	MV_A/C	50	1.5	1.5
Meningococcal A/C/W/Y	lyophilized	SC	MV_A/C/W/Y	10	2.5	2.5
Meningitis W135	lyophilized	SC	MV_W135	N/A	N/A	
Meningitis A conjugate	lyophilized	SC	Men_A	10	3.8	
Rota vaccine	liquid	Oral	Rota	1	111.6	
Pneumo. conjugate vaccine 7 - valent	liquid	IM	PCV-7	1	N/A	
Flu vaccine	liquid		Flu	N/A	N/A	

Source : International shipping guidelines, rev 2005 and Unicef, forecast 2006

Storage volumes for refrigerators and freezers

Equipment identification					Type of refrigerant	Temperature zone	Net storage volume (litres)	
Designation	Make	Model	Code PIS	Type			refrigerator	freezer
Refrigerator & freezer	BP Solar	VR50F	E3/37-M	SE	R134a	HZA	17.5	5.0
Refrigerator & freezer	Bright Light Solar	PS65	E3/106-M	SE	R134a	HZA	37.5	16.0
Refrigerator & freezer	Bright Light Solar	PS40	E3/109-M	SE	R134a	HZA	18.0	4.0
Icelined refrigerator	Dometic	TCW 3000	E3/107-M	CR	R134a	HZA	126.5	
Refrigerator & freezer	Dulas	VC-150 F	E3/79-M	SE	R134a	HZA	85.0	24.0
Refrigerator & freezer	Dulas	VC-65 F	E3/103-M	SE	R134a	HZA	37.5	16.0
Refrigerator	Electrolux	RCW 42 EG / CF	E3/21-M	AR	NH3	TZA	10.5	1.6
Refrigerator	Electrolux	RCW 42 EK / CF	E3/22-M	AR	NH3	TZA	18.2	1.2
Icelined refrigerator	Electrolux	TCW 1152 / CF	E3/24-M	ILR	R134a	HZA	169.0	
Refrigerator & freezer	Electrolux	RCW 42AC / CF	E3/30-M	CR	R134a	HZA	12.0	12.0
Refrigerator & freezer	Electrolux	RCW 42DC / CF	E3/31-M	SE	R134a	HZA	14.0	14.0
Icelined refrigerator	Electrolux	TCW 1990	E3/62-M	ILR	R134a	HZA	37.5	
Icepack freezer	Electrolux	FCW 20 EG / CF	E3/72-M	AF	NH3	TZA		14.0
Icepack freezer	Electrolux	FCW 20 EK / CF	E3/73-M	AF	NH3	TZA		14.0
Icepack freezer	Electrolux	TFW 800	E3/80-M	CF	R134a	HZA		145.0
Refrigerator & freezer	Electrolux	RCW 50 EG / CF	E3/88-M	AR	NH3	HZA	24.0	
Refrigerator & freezer	Electrolux	RCW 50 EK	E3/91-M	AR	NH3	HZA	24.0	
Refrigerator & freezer	Electrolux	RCW 50DC / CF	E3/93-M	SE	R134a	HZA	24.0	8.0
Refrigerator & freezer	Electrolux	RCW 50 AC	E3/94-M	CR	R134a	HZA	24.0	8.0
Vaccine/icepack freezer	Electrolux	FCW 300	E3/99-M	CF	R134a	HZA		264.0
Vaccine/icepack freezer	Electrolux	FCW 200	E3/100-M	CF	R134a	HZA		144.0
Refrigerator & freezer	Fortum AES	CFS49 ISI	E3/70-M	SE	R134a	HZA	20.0	8.0
Refrigerator & freezer	Kyocera Solar	VaccPack X L 2	E3/104-M	SE	R134a	HZA	21.0	24.0
Refrigerator & freezer	Kyocera Solar	VaccPack X L 6	E3/105-M	SE	R134a	HZA	60.0	16.0
Icelined refrigerator	LEC RefrigerationPLC	VC 139 F	E3/64-M	ILR	R134a	HZA	107.5	
Refrigerator & freezer	Norcoast	NRC 30-10	E3/65-M	SE	R134a	HZA	15.5	12.2
Refrigerator & freezer	Norcoast	Model 120-30	E3/92-M	SE	R134a	HZA	63.0	30.0
Refrigerator & freezer	PT. Dilihan Glory	DOVLINE	E3/110-M	CR	R134a	TZA	16.0	
Refrigerator & freezer	Sibir	V 170 GE	E3/84-M	AR	NH3	HZA	55.0	36.0
Refrigerator & freezer	Sibir	V 170 EK	E3/85-M	AR	NH3	HZA	55.0	36.0
Refrigerator & freezer	Sibir	V 110 GE	E3/86-M	AR	NH3	HZA	17.0	15.0
Refrigerator	Sibir	V 110 KE	E3/87-M	AR	NH3	HZA	17.0	15.0
Refrigerator & freezer	Solamatic	PVR150	E3/101-M	SE	R134a	HZA	30.0	12.0
Refrigerator & freezer	Sun Frost	RFVB-134a	E3/77-M	SE	R134a	HZA	38.7	32.5
Refrigerator & freezer	TATA BP Solar	TBP VR 50	E3/83-M	SE	R134a	HZA	18.0	5.0
Icelined refrigerator	Vestfrost	MK 144	E3/57-M	ILR	R134a	HZA	45.0	
Icelined refrigerator	Vestfrost	MK 074	E3/75-M	ILR	R134a	HZA	20.0	
Icelined refrigerator	Vestfrost	MK 204	E3/81-M	ILR	R134a	HZA	63.0	
Icelined refrigerator	Vestfrost	MK 304	E3/82-M	ILR	R134a	HZA	108.0	
Vaccine/icepack freezer	Vestfrost	MF 114	E3/96-M	CF	R134a	HZA		72.0
Vaccine/icepack freezer	Vestfrost	MF 214	E3/97-M	CF	R134a	HZA		192.0
Vaccine/icepack freezer	Vestfrost	MF 314	E3/98-M	CF	R134a	HZA		264.0
Refrigerator & freezer	Zero	PR 245 K/E	E3/89-M	AR	NH3	TZA	18.0	20.0
Refrigerator & freezer	Zero	GR 245 G/E	E3/90-M	AR	NH3	TZA	18.0	20.0
Icepack freezer	Zero	PF 230 IP K/E	E3/95-M	AF	NH3	HZA		144.0
Refrigerator & freezer	Zero	GR 265 K/E	E3/102-M	AR	NH3	HZA	16.0	
Refrigerator & freezer	Zero	PR 265 K/E	E3/108-M	AR	NH3	HZA	37.5	9.6

Source : *WHO/UNICEF Product Information Sheets*, WHO/V&B/00.13 - Last updated Feb 2007

TZA = temperate zone appliance
HZA = hot zone appliance
CZA = cold zone appliance

CF = compr freezer
AR = absop refrigerator
CR = compr refrigerator

AF = absop freezer
SE = solar equipment

Unit volumes for safe-injection equipment

Safe-injection equipments	Units per box	Volume (cm^3/unit)
AD Syringes 0.05 ml for BCG	100	60
AD Syringes 0.1 ml for BCG	100	60
AD Syringes 0.5ml	100	60
Syringes 2 ml for dilution BCG/Hib	100	66.25
Syringes 5 ml for dilution Msls/YF	100	66.25
Syringes 10 ml for dilution YF/Meningitis	100	66.25
Safety boxes, 5 litres	25	880
Safety boxes, 10 litres	25	1333.33
Droppers		

Source : PIS/PQS, 2005

Annex 6: Example of a cold-chain equipment inventory form

DISTRICT: _____ **YEAR:** _____

COLD-CHAIN EQUIPMENT INVENTORY												
Information relating to the location					Information relating to the cold-chain equipment							
Name	Type of facility	Total population	Electricity (Y/N)	Electricity ≥ 8hrs in 24 hours	Manufacturer	Model	Serial number	Current working status	Date of last assessment	Energy source (G=gas K=kerosene E=electric S=solar)	Year of installation	Year of planned replacement

Annex 7 : Example of a form to calculate transportation needs

This form (overleaf) provides an example of how to calculate the number of cold boxes and dry-storage space needed to transport vaccines and safe-injection equipment.

Complete the form as outlined below.

Column A :	Write the names of districts in the province and their target population.
Column B :	Include all vaccines in the schedule.
Column C :	Calculate the monthly needs by multiplying target population by the waste multiplication factor (WMF) and the number of doses in the schedule, then dividing by 12.
Columns D :	For each vaccine include the presentation – i.e. the number of doses in one vial.
Columns E, F :	Include packed volume for each vaccine and diluents in cubic centimetres.
Column G, H :	Include volume of vaccines and diluents in litres by multiplying packed volume per dose (column E, F) by the total number of monthly doses needed (column C), then dividing by 1000.
Column I, J :	Add the total volume for each vaccine and diluent to get the total volume needed for all vaccines and diluents.
Column K :	Calculate total number of cold boxes needed by dividing the total volume of vaccines (column I) by the unit volume of a cold box (20 litres).
Columns L, N, P, Q :	Insert the quantity needed for each type of AD syringe and reconstitution syringe.
Columns M, O :	Multiply the unit volume of each type of injection equipment by the quantity of each needed.
Column R :	Add the totals of each type of reconstitution syringe then multiply the total sum by 66.25 (unit volume of reconstitution syringes).
Column S :	Determine the number of safety boxes needed by calculating the total of all the syringes needed then dividing that sum by the capacity of a 5-litre safety box (100 syringes).
Column T :	Determine the volume occupied by folded safety boxes by multiplying total number of safety boxes needed by 880.
Column U :	Calculate the total volume of safe-injection equipment by totalling the volume of each safe-injection equipment type and then converting that sum to cubic metres by dividing by 1 000 000.

Estimating cold boxes and dry storage space required to distribute vaccines and safe-injection equipment

INDUS DISTRICT	Vaccines	Monthly vaccines (doses)	Packed doses per vial	Packed volume per dose (cm³)		Volume of vaccines and diluents (litres)		Total volume of vaccines & diluents (litres)		No. of cold boxes 20 litres	Quantities and volume of safe-injection equipment to be disctributed									Total volume of safe-injection equipment (m³)
											AD_0.05 ml		AD_0.5 ml		Mixing_2 ml	Mixing_5 ml	Mixing syringes	Safety box		
				vaccines	diluents	vaccines	diluents	vaccines	diluents		quantity	volume	quantity	volume	quantity	quantity	volume	quantity	volume	volume
A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U
Target population	Name	A*WMF*no of doses/12				C*E/1000	C*F/1000	Sum G	Sum H	I/20	Tar*1.1/12	SumL*53	Tar*1.1/12	SumN*60	C/D	C/D	Sum (P,Q)/66.25	Sum L,N,P Q/100	S*880	Sum(M, O, R, T) /1000000
30,000	BCG	5,000	20	1.2	0.7	6	4				2,750				250					
	OPV	13,300	10	2.0		27														
	DTP-HepB-Hib	7,875	1	12.9		102							8,250							
	Measles	3,325	10	3.5	4.0	12	13						2,750			333				
	YF	3,325	10	2.5	6.0	8	20						2,750			333				
	TT	6,650	10	2.0		13		167	37	9		145,750	5,500	1,155,000			60,619	229	201,652	1.6

The World Health Organization has provided technical support to its Member States in the field of vaccine-preventable diseases since 1975. The office carrying out this function at WHO headquarters is the Department of Immunization, Vaccines and Biologicals (IVB).

IVB's mission is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases. The Department covers a range of activities including research and development, standard-setting, vaccine regulation and quality, vaccine supply and immunization financing, and immunization system strengthening.

These activities are carried out by three technical units: the Initiative for Vaccine Research; the Quality, Safety and Standards team; and the Expanded Programme on Immunization.

The Initiative for Vaccine Research guides, facilitates and provides a vision for worldwide vaccine and immunization technology research and development efforts. It focuses on current and emerging diseases of global public health importance, including pandemic influenza. Its main activities cover: i) research and development of key candidate vaccines; ii) implementation research to promote evidence-based decision-making on the early introduction of new vaccines; and iii) promotion of the development, evaluation and future availability of HIV, tuberculosis and malaria vaccines.

The Quality, Safety and Standards team focuses on supporting the use of vaccines, other biological products and immunization-related equipment that meet current international norms and standards of quality and safety. Activities cover: i) setting norms and standards and establishing reference preparation materials; ii) ensuring the use of quality vaccines and immunization equipment through prequalification activities and strengthening national regulatory authorities; and iii) monitoring, assessing and responding to immunization safety issues of global concern.

The Expanded Programme on Immunization focuses on maximizing access to high quality immunization services, accelerating disease control and linking to other health interventions that can be delivered during immunization contacts. Activities cover: i) immunization systems strengthening, including expansion of immunization services beyond the infant age group; ii) accelerated control of measles and maternal and neonatal tetanus; iii) introduction of new and underutilized vaccines; iv) vaccine supply and immunization financing; and v) disease surveillance and immunization coverage monitoring for tracking global progress.

The Director's Office directs the work of these units through oversight of immunization programme policy, planning, coordination and management. It also mobilizes resources and carries out communication, advocacy and media-related work.

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