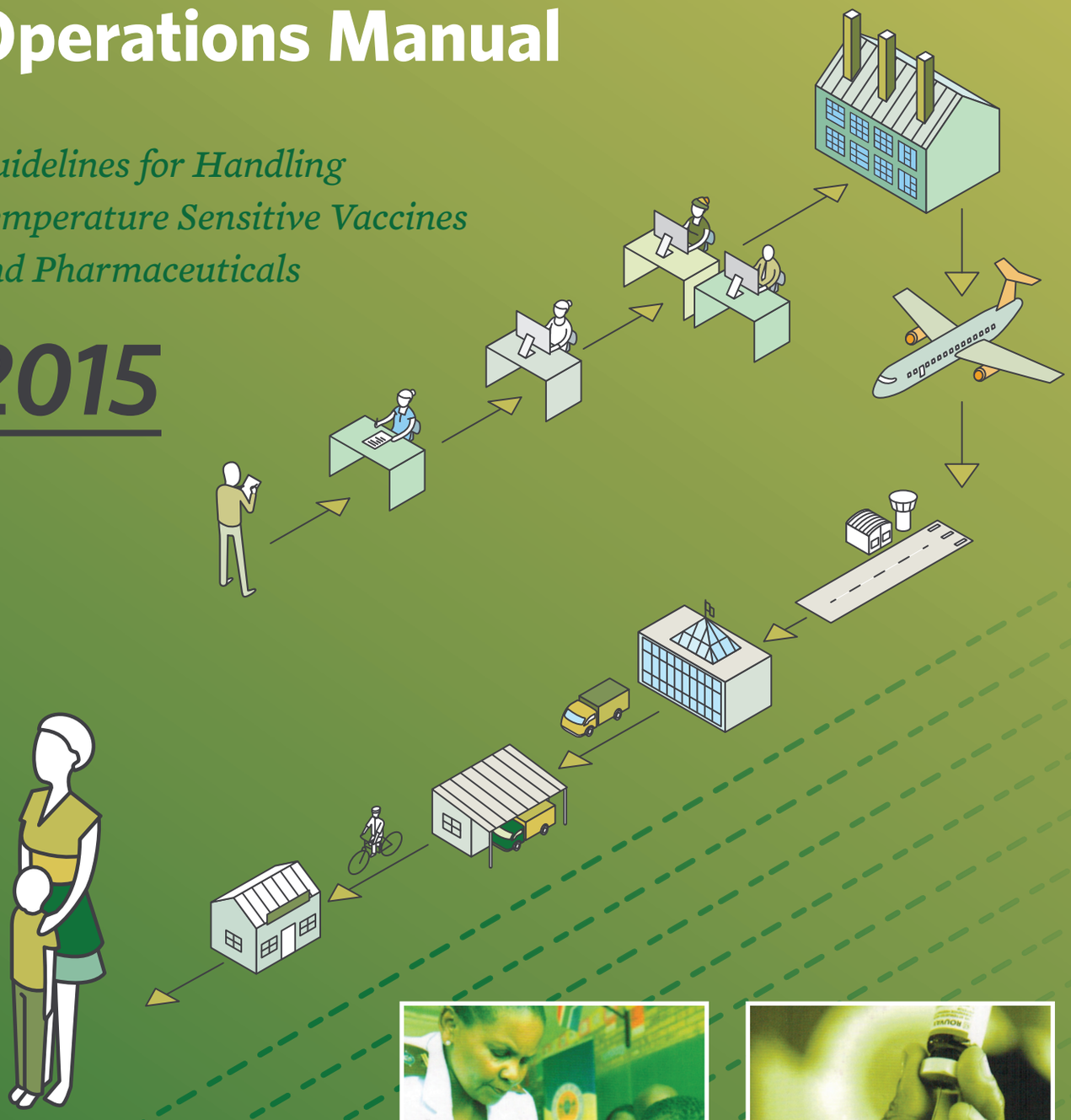
Cold Chain and Immunisation Operations Manual

Guidelines for Handling Temperature Sensitive Vaccines and Pharmaceuticals

2015



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A long and healthy life for all South Africans

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Foreword

Foreword to the 2015 edition of Cold Chain and Immunisation Operations Manual.

The first South African Cold Chain Manual was the first comprehensive guideline for the management of vaccines and related substances in South Africa. This manual is the third edition and is a guideline for managing vaccines and their associated products at all levels of health care service. Each healthcare worker handling and or managing vaccines should own a Cold Chain Manual and use it as a reference to the handling and management of vaccines and related substances.

The manual is intended for both private and public sector healthcare vaccinators but some of the sections and examples are specific to the public sector because that is where the majority of childhood vaccinations are given. It will help healthcare workers to determine how much vaccine and related substances they need to run a successful immunisation facility, how to manage its storage, distribution and replacement.

All facilities are expected to change to vaccine specific fridges if they have not yet done so because these fridges are designed to keep a more constant temperature and have a longer holdover time when there is power failure. These vaccine specific fridges are also more efficient and thus cost less to run.

Much of the content and concepts in this manual reflect policy and documentation from WHO and UNICEF Expanded Programme on Immunisation (EPI). Thanks to WHO and UNICEF staff and consultants for their guidance and contribution in the writing of this Cold Chain Manual.

Each facility should have a copy of this manual and make sure that vaccines are kept potent for vaccination against Vaccine Preventable Diseases.

MS MP MATSOSO
DIRECTOR-GENERAL: HEALTH
DATE: 20/01/2016

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Glossary of terms

Adjuvant
An addition (auxiliary help) to the vaccine – used in killed vaccines, either viral or bacterial, such as DTP, Td, TT and Hep B. Vaccines containing an adjuvant are sensitive to freezing and must not be used if they have been frozen.

Amortised cost
The gradual writing off (depreciation) of the initial capital cost of an item. In the case of EPI, it is the refrigerator or freezer.

Catchment population
The number of people served by a particular health facility in the surrounding community.

Clinic
The facility in which the health service is offered to the community.

Cohort
A well-defined group of people who have had a common experience or exposure and who are then followed up for the incidence of new diseases or events as in a cohort or prospective study e.g. A group of babies born during a particular period or year is called a cohort.

Cold Chain
A system consisting of people, equipment and heat-sensitive pharmaceuticals such as vaccines, which ensures that the correct quantity of potent vaccine/ medicine reaches the children, women or men who need it. The temperature of these items must be maintained within a specified temperature range from the time of production through to the administration thereof.

District/Sub-district
The health level managed by the district/ Sub-district manager.

Flocculation/ Granulation
Granular particles (floccules) produced after certain vaccines are frozen. They may or may not be visible to the naked eye, but will sediment faster than their unfrozen counterparts.

Provincial
The management or central level of the health service within a province.

Reverse cold chain
The process of maintaining the cold chain when heat sensitive items are stored and transported in the reverse direction i.e. upwards from the clinic to a depot or laboratory. This process is also used for transporting specimen samples.

Sub-provincial
The health service level below provincial – could be district or sub-district.

Supplier
The institution supplying the vaccines and other pharmaceuticals or medical related items. This could be the manufacturer, distributor, provincial or sub-provincial depots or the district hospital.

Vaccine presentation
The number of doses within a specific vial size of vaccine – could be single dose or multi-dose (10 or 20 doses).

Wastage – *avoidable*
The number of doses of vaccine wasted through avoidable circumstances such as a break in the cold chain, vaccines expiring in stock or frozen in storage or during transportation in cold boxes.

Wastage – *unavoidable*
The number of doses of vaccine wasted through unavoidable circumstances. This could be as a result of the EPI policy or as a result of the vaccine type. An example of the latter is measles vaccines, which once reconstituted, may only be used within a six-hour immunisation session.

Another example is vaccine wasted due to the vaccine presentation not delivering the number of actual doses as stated by the manufacturer e.g. OPV.

Abbreviations

BCG *Bacillus Calmette-Guérin*
CCM *Cold Chain Monitor card*
DoH *Department of Health*
DTwP *Diphtheria Tetanus Pertussis (whole cell) vaccine*
DTaP *Diphtheria Tetanus Pertussis (acellular) vaccine*
EPI *Expanded Programme on Immunisation*
EEFO *Earliest Expiry, First Out*
FW *Freeze Watch card*
Hep B/HBV *Hepatitis B Vaccine*
Hib *Haemophilus influenzae type b vaccine*
NBC *New-born children*
OPV *Oral Polio Vaccine*
PCV *Pneumococcal Conjugate Vaccine*
PVC *Polyvinyl chloride (plastic)*
RSA *Republic of South Africa*
RH *Rhesus factor*
RV *Rotavirus Vaccine*
SIA *Supplementary Immunisation Activity*
TT *Tetanus Toxoid vaccine*
Td *Tetanus vaccine with 1/2 strength diphtheria vaccine*
UNICEF *United Nations Children's Fund*
VVM *Vaccine Vial Monitor*
WHO *World Health Organisation*
YF *Yellow fever vaccine*

1. INTRODUCTION

1.

Immunisation is the most precious gift that a health care worker can give to a child. Immunisation remains one of the most cost effective preventative health interventions presently known.

The purpose of the Expanded Programme on Immunisation in South Africa, EPI (SA), is to ensure efficient and nation-wide control of vaccine preventable diseases through the provision of effective immunisation services at all health care facilities. Every member of the immunisation team from nurse to programme manager helps to prevent death and reduce suffering from diseases of childhood that can be prevented by immunising children and women.

For an immunisation programme to be effective it must have a sound plan based on epidemiological data, a supportive public which wishes to be immunised and operations management which can ensure that the plans and procedures are implemented effectively.

The key areas of operation management include logistics support on vaccine management and monitoring, cold chain management and immunisation safety.

A proper cold chain is a temperature-controlled supply chain that includes equipment and procedures used in the transport and storage and handling of vaccines from the time of manufacturer to administration of the vaccine. Maintenance of the cold chain during storage and distribution of vaccines remains the most critical element of an immunisation programme. Significant amount of vaccine can be damaged if not properly handled and, therefore, putting the immunisation services of an entire country at risk and incurring huge financial loss.

To avoid the risk of such failure, the procured equipment must be of the highest international standards and should be installed, operated and maintained by trained and skilled personnel at all levels.

1.1 Why an operations manual?

The need for an operation manual was based on reviews the National Immunisation Programme in the past (1994), which revealed the following main areas of concern in the proper management of the programme:

- Establish clear management structures
- Assure quality of vaccine at the point of use
- Ensure safety of injections
- Improve the cost effectiveness of the programme

It has become clear that each level of vaccine operations management suffers from problems which cause a breakdown in the effective provision of a successful immunisation service. These problems may be at clinic level where in some cases the size of target populations are unknown, refrigeration is unsatisfactory, maintenance of equipment irregular or non-existent, gas cylinders are stolen or communication systems poor. Conditions at the storage depots have not been ideal either, and limited studies have shown that during transport and storage, the cold chain is often broken. Wastage of vaccines is very often not recorded, whether avoidable or not, making accurate estimations and budgeting for vaccines problematic.

A recent (2011) post introduction evaluation by internal and external monitors found out that

- Several vaccine shipments have arrived in South Africa with changed freeze monitors
- The potential freezing of vaccines remains a major risk due to fridges that are irregularly monitored or adjusted and through solidly frozen ice- and gel packs used during immunisation sessions and during transport.

Hence, the purpose of this cold chain manual is to provide guidelines and standards for organization of operations management, vaccine storage and distribution. It also helps assess weaknesses in equipment and operating procedures to make the necessary improvements.

1.2 What is new in this edition

This edition has updated information on handling of the new vaccines. The guideline is updated to be in line with the new Effective Vaccine Management (EVM) tool which combines previous versions of Effective Vaccine Store Management (EVSM) tool and Vaccine Management Assessment tool (VMA). The purpose of the EVM is to encourage countries to procure and maintain equipment and to adopt management and training practices that fully protect vaccines at all levels. It sets out nine key criteria that a national EPI system should ensure implementation in the previous year:

1. Pre-shipment and arrival procedures ensure that every shipment from the vaccine manufacturer reaches the receiving store in satisfactory condition and with correct paperwork (for primary stores)

2. All vaccines and diluents are stored and distributed within WHO-recommended temperature ranges.

3. Cold storage, dry storage and transport capacity is sufficient to accommodate all vaccines and supplies needed for the programme.

4. Buildings, cold chain equipment and transport systems enable the vaccine and consumables supply chain to function effectively.

5. Maintenance of buildings, cold chain equipment and vehicles is satisfactory.

6. Stock management systems and procedures are effective.

7. Distribution between each level in the supply chain is effective.

8. Appropriate vaccine management policies are adopted and implemented.

9. Information systems and supportive management functions are satisfactory.

Provincial cold chain and vaccine logistic managers should conduct periodic self-assessment and ensure that appropriate attention is given to the above key criteria in effective vaccine management. (The background document and assessment tool can be found at *http://www.who.int/immunisation_delivery/systems_policy/EVM-background.pdf)*

1.3 Who is this manual written for?

This manual is designed to assist all those who have a responsibility for implementing immunisation policy. These include:

- National Managers, both EPI and vaccine
- Provincial vaccine and EPI co-ordinators
- Depot or stores managers
- Health care professionals
- Health care providers.

This manual formulates policy and provides a nation-wide standardised guideline on:

- Acceptable operations management,
- Appropriate procedures and
- Standard Operating Procedures

Each member of the immunisation team - not only the operations manager - should have a clear view on these matters and we would encourage everyone involved in the immunisation programme to read and understand this guideline.

1.4 How to use this manual

This manual should be used in conjunction with the Norms and Standards for Service Delivery guidelines produced by Pharmaceutical Programmes and Planning, and the corresponding provincial guidelines which include all of the SOPs.

Many aspects of the cold chain operations are applicable to all levels of management. However, in some cases, practices may differ between the different levels and it has been described in the manual at three levels, shown in three columns.

The table of contents enables quick access to any aspect covered in this manual and it is requested that this guideline is kept to hand for easy reference in all situations.

2. Operations management

2.

2.1 Operations staff

At each level, operations management should always be the responsibility of one fully trained person with a suitable back-up. This person should be trained by the provincial training team and supervised by a pharmacist. Operations management includes the cold chain. The Cold Chain Cycle is illustrated in Figure 2.1

Vaccine quality can only be assured if the product is correctly stored and handled from the point of manufacturing to the point of use. In addition to skilled manpower and appropriate equipment, the operation management should keep detailed records to ensure that the quality of vaccines has been maintained at all levels.

Vaccine management includes two critical functions that must be undertaken by a skilled, competent and motivated team to ensure adequate availability of high-quality vaccines for immunisation service delivery. These are:

2.2 Managerial functions

The managerial functions of vaccine management include the following:

- Identifying and estimating needs for vaccines and immunisation-related equipment in accordance with programme plans and projections
- Coordinating, preparing and ordering vaccines and injection equipment in a timely fashion
- Overseeing systems for optimal use and maintenance of major cold chain equipment and transportation
- Establishing SOPs for the clearance and receipt of vaccines and immunisation-related equipment, including completion of Vaccine Arrival Reports
- Receiving vaccines and handling of stocks; Clearing vouchers and relevant documentation required for the requisition and distribution of vaccines and immunisation-related equipment to lower levels to ensure that adequate quantities have been delivered and can be referenced
- Providing technical support to provincial and district level managers
- Report writing and record-keeping of archived documents

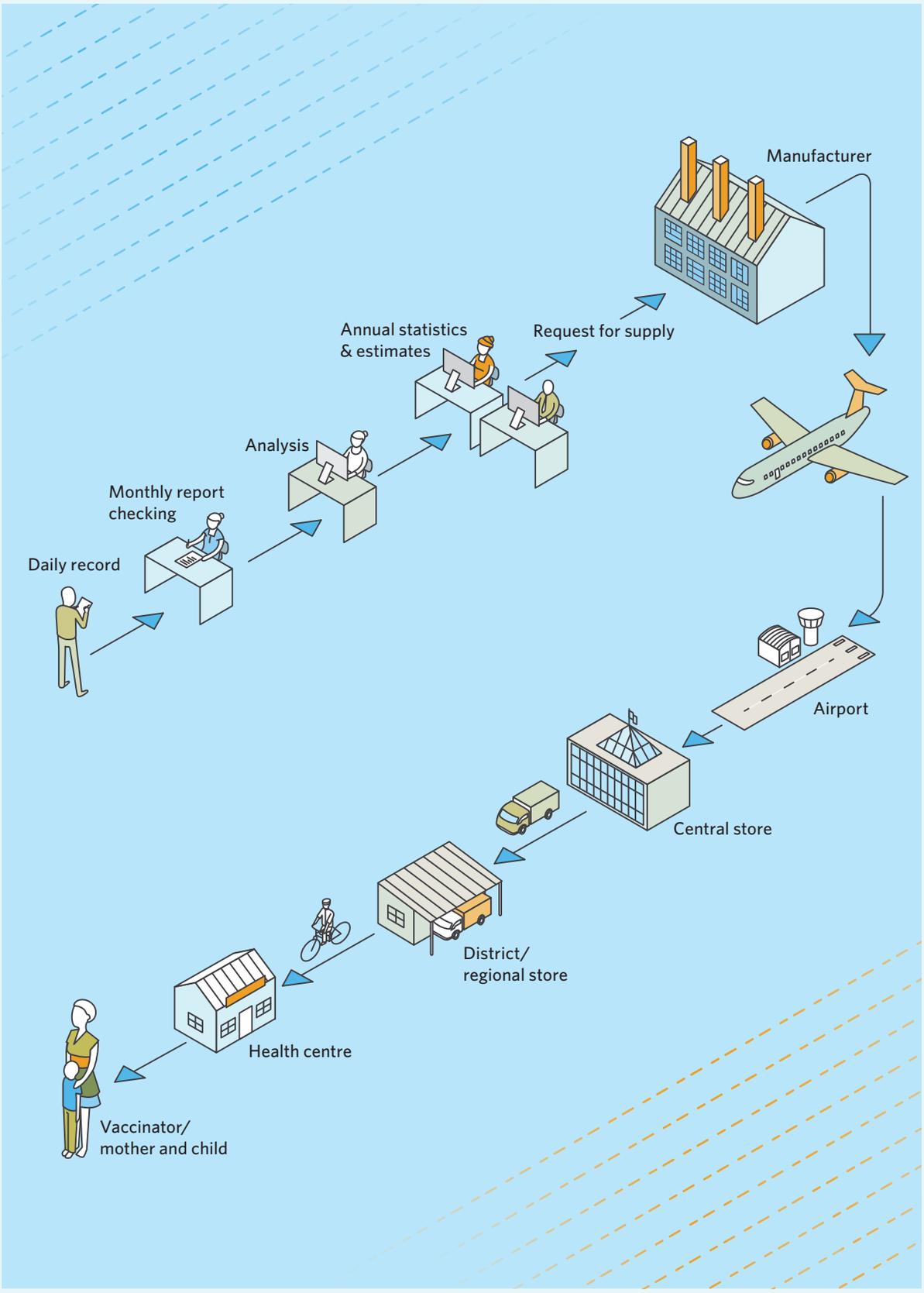
2.3 Operational functions:

The operational functions of vaccine management include the following:

- Carrying out delivery of vaccines and immunisation related equipment in consultation with the management
- Sorting of vaccines and immunisation related equipment as appropriate
- Updating stock records (individual stock sheets per batch)
- Monitoring storage temperatures and other conditions as appropriate
- Conducting first-level maintenance of cold chain equipment
- Informing management of any apparent problems.

Typical post descriptions for cold chain and vaccine logistics managers and other responsible people are shown for each level so that staff may understand

Figure 2.1
Cold Chain Cycle



their responsibilities and also see how those responsibilities compare with their counterparts at other levels. See Appendix 2: Job Description, National Cold Chain and Vaccine Manager for National Cold Chain Manager's job description.

2.4 Job Descriptions

	Provincial Level	Sub Provincial/District Level	Clinic Level
	Provincial Cold Chain and Operations Manager	*Sub-Provincial/district person responsible for Cold Chain & Vaccine Management*	*Clinic person responsible for Cold Chain management*
a)	Provide management support to the EPI manager including assessment of the logistical implications resulting from programmatic decisions	Provide management support at sub provincial level	Ensure proper management of logistical aspects of EPI in the clinic
b)	Ensure that relevant updated cold chain information is available to all staff involved in the cold chain	Ensure that relevant updated cold chain information is available to all staff involved in the cold chain	Ensure that relevant updated cold chain information is available to all staff involved in the cold chain
c)	Ensure adequate formal and in-service training of all staff involved in vaccine management	Ensure adequate formal and in-service training of all staff involved in vaccine management.	Ensure that staff implement EPI and vaccine management training given.
d)	Prepare estimates (including budget) of vaccines and related medical items necessary for immunisation (syringes, needles, etc.)	Provide the Provincial Vaccine Manager with required budgetary data	Provide district person responsible with required budgetary data
e)	Adjust estimates from immunisation data received to include acceptable levels of wastage, and report to the EPI manager and the national cold chain manager	Provide the Provincial Vaccine Manager with required wastage data	Provide district person responsible with required wastage data
f)	In conjunction with the sub-provincial/district vaccine managers, co-ordinate, monitor and approve orders for vaccines, and medical related items	In conjunction with the Provincial vaccine managers, co-ordinate, monitor and approve orders for vaccines, and medical related items	Provide district person responsible with required vaccine and medical related item stock data
g)	In conjunction with the provincial EPI manager and the main provincial medical stores, co-ordinate and plan the logistics for the cost-effective distribution of vaccine	Provide the Provincial Vaccine Manager with requirement distribution data	Provide district person responsible with required data on receipt of vaccine and medical related items
h)	Maintain and ensure a constant cost effective supply/storage of heat sensitive products and medical related items for immunisation	Maintain and ensure a constant cost effective supply/storage of heat sensitive products and medical related items for immunisation	Maintain and ensure a constant cost effective supply/storage of heat sensitive products and medical related items for immunisation

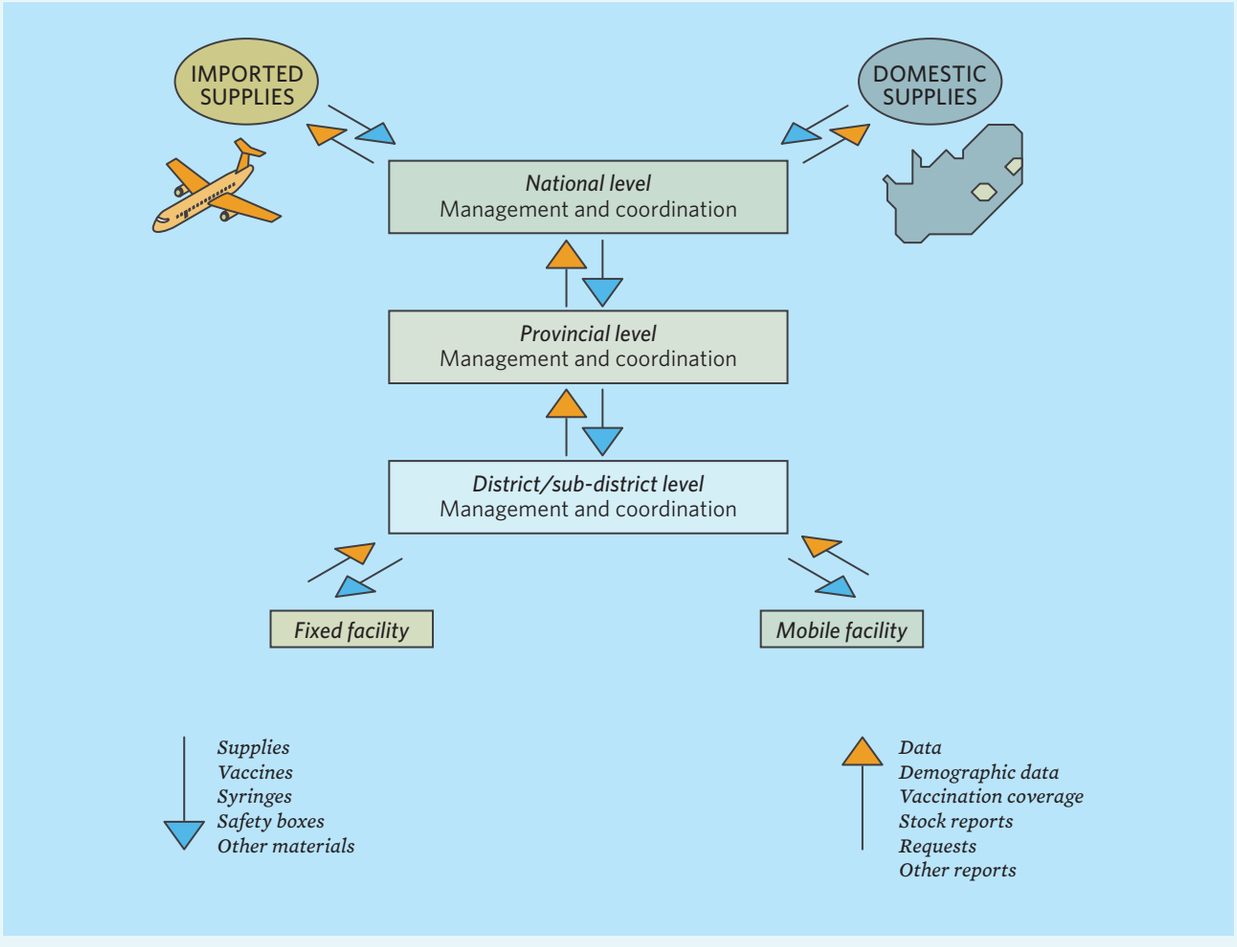
i)	Monitor the quantity used and financial expenditure of vaccines and medical related items for immunisation and report monthly to the provincial EPI manager and the national cold chain manager	Monitor the quantity used (including financial expenditure incurred)of vaccines and medical related items for immunisation and report monthly to the provincial/ district vaccine manager	Monitor the quantity of vaccines and medical related items used for immunisation and report monthly to the district person responsible
j)	Ensure the efficient usage of vaccines by limiting wastage and monitoring activity	Ensure the efficient usage of vaccines by limiting wastage and monitoring activity	Ensure the efficient usage of vaccines by limiting wastage and monitoring activity
k)	Ensure that a needs-analysis for adequate storage equipment is done regularly, funds estimated and reported to the provincial EPI manager and the national cold chain manager	Ensure that data requested for a needs-analysis for adequate storage equipment is provided when requested	Ensure that data requested for a needs-analysis for adequate storage equipment is provided when requested
l)	Assess staff requirements at different levels for the sub-provincial vaccine managers for EPI and monitor training needs	Provide data for assessing staff requirements at different levels for the district level staff	Provide data for assessing staff requirements at different levels for the clinic level staff
m)	Liaise with the provincial EPI manager on disease outbreaks, and have contingency plans ready for these events	Provide the Provincial Vaccine Manager with required data and implement contingency plans	Provide district manager with required data and implement contingency plans
n)	In the event of a cold chain failure at any level, make a decision on action to be taken, and/or liaise with the national cold chain manager	In the event of a cold chain failure, make a decision on action to be taken, and/or liaise with the Provincial vaccine manager	In the event of a cold chain failure, make a decision on action to be taken, in collaboration with the responsible district person
o)	Ensure safe logistics for disposal and destruction of used sharps and syringes, and relay tender requirements for sharps containers, where necessary, to the national cold chain manager	Ensure safe logistics for disposal and destruction of used sharps and syringes, and relay tender requirements for sharps containers, where necessary, to the Provincial vaccine manager	Ensure safe logistics for disposal and destruction of used sharps and syringes, and report destroyed quantities of sharps containers to the district person responsible
p)	Conduct regular stock and documentation checks (audit) of all vaccines and medical related items	Conduct regular stock and documentation checks (audit) of all vaccines and medical related items	Conduct regular stock and documentation checks (audit) of all vaccines and medical related items
q)	Conduct annual audits of vaccines, medical related items and equipment	Conduct annual audits of vaccines, medical related items and equipment	Conduct annual audits of vaccines, medical related items and equipment

2.5 Organisation of EPI logistics

The purpose EPI logistics team is to ensure that supplies and personnel are in the right place at the right time with the appropriate quantity and quality through the most cost-effective means to satisfy immunisation needs at all levels in a country. For the EPI programme to be effective it must have efficient logistics. The logistics will only be efficient if there is a team of staff designated at each level to ensure that operations are fully integrated with the EPI Programme. A well-managed and efficient logistics system can help save on programme costs without sacrificing the quality of service delivery. Poorly managed logistics systems can lead to high and/or unnecessary vaccine wastage, stock outs, or improper management of waste, resulting in significant operational programme costs, as well as a negative impact on public health

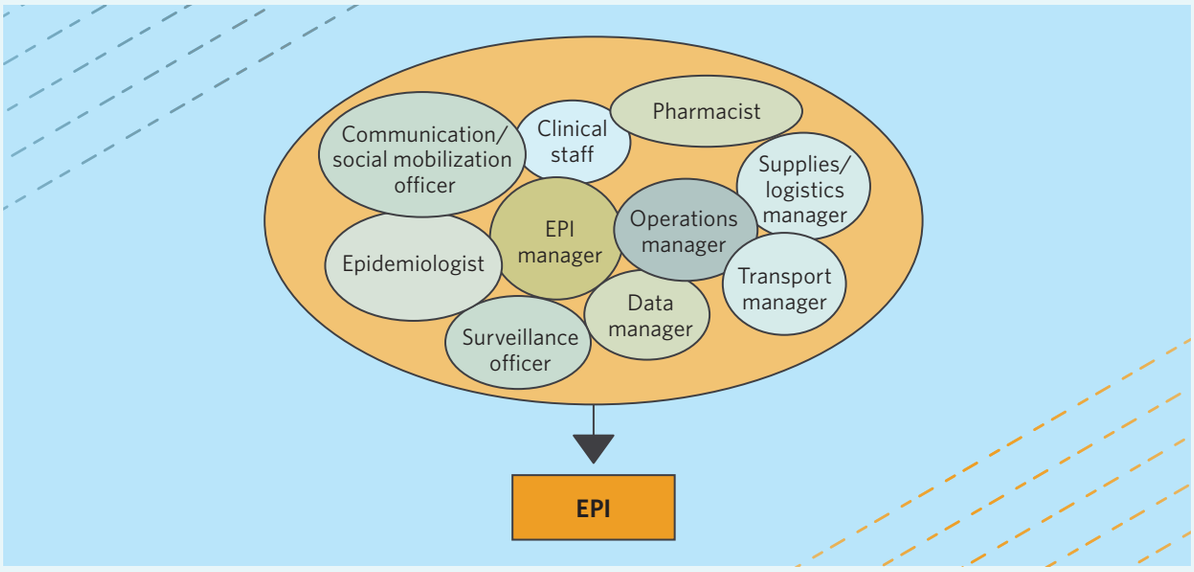
The structure and interdependence of such a model is illustrated in Figure 2.2

Figure 2.2
The Organisation of EPI Logistics



The teamwork required for ensuring the management and co-ordination is illustrated in Figure 2.2 is shown in Figure 3. The figure illustrates the symbiotic relationship that should exist between the EPI manager and the operations manager. It also shows how the other team members involved in the provision of immunisation services, relate to each other to make up the overall management of EPI. Without the effective functioning of each component and without the dynamic links between each of them, EPI management will never be effective.

Figure 2.3
Teamwork builds EPI Operations



Such kind of teamwork is essential at all levels for effective delivery of EPI services. Each level of EPI management is dependent upon the effective functioning of the level below it, thus the National level is dependent on the Provincial level which in turn depends on the sub-provincial level which itself relies on the clinics. Without sound and reliable management and logistics at the clinics EPI cannot be effective and efficient.

2.6 Logistics planning

There are two basic options for vaccine supply, a fast cold chain or a slow cold chain. The fast cold chain relies on speed to limit the inadequacies of vaccine storage, distribution and handling on the vaccines. Fast cold chains may incur greater cost in distribution, but these costs are offset in part by having a smaller quantity of vaccine in the pipeline. The slow cold chain will reduce the cost of distribution but increase the volume of vaccine in the pipeline. The requirement of logistics planning is to choose the balance between fast and slow cold chains, which will ensure availability of potent vaccine at a least cost.

Factors to be considered for appropriateness of fast and slow cold chain:

Fast Cold chain	Slow Cold chain
• Unreliable refrigeration at clinic level	• Reliable refrigeration at clinic level
• Weak management at clinic level	• Strong management at clinic level
• Cost-effective and reliable distribution	• Expensive and less reliable distribution
• Short distances	• Long distance
• High vaccine cost	• Low vaccine cost

3. Procurement or requisition of vaccines and other supplies

3.

The purchase of vaccines is a complex process that requires specialized knowledge in order to ensure vaccine quality. As biologicals, the composition of vaccines is different from that of drugs in several respects and therefore their procurement requires additional considerations. Hence an independent National Regulatory Authority (NRA), which holds competency for vaccine regulation is responsible to license vaccines for use in country, establish procedures for vaccine lot release and institute a post-marketing surveillance system of vaccine performance in the field. In South Africa, the Medicines Control Council (MCC) is the national authority tasked with the above responsibility.

The national EPI programme is responsible for defining the specifications of vaccine products needed and forecasting the multi-year vaccine demand.

The procurement procedure should also ensure that international packaging standards and processes be part of the tendering specifications.

Procurement of vaccine fridges and other cold chain equipment should also follow international (WHO/PQS) specifications.

Estimating needs:

Good immunisation management begins with the correct estimation of vaccines and related products needed for the immunisation programme.

3.1 Vital considerations

- Vaccine producers require accurate vaccine forecasts to provide sufficient quantities
- Vaccines are becoming increasingly expensive, particularly new vaccines

Global capacity for vaccine production is limited.

3.2 Advantages of obtaining accurate forecasts of vaccine needs

- More efficient control of immunisation programmes by their managers
- Elimination of inventory shortages and/or over-stocking of vaccines
- Improvement of the capacity of districts to develop more accurate micro-plans.
- Improvements in efficiency of vaccine use, and reduction of wastage
- More accurate estimates of financial resources when creating budget lines for purchase of vaccines.
- Assists in monitoring the progress of immunisation in relation to the target coverage.

3.3 Common problems

- Vaccine needs are normally estimated at the provincial level using historic data

In provinces and districts where there is no focal person responsible for vaccine management, vaccine need forecasting is challenging and can be unreliable

3.4 Methods of estimating vaccine requirement

There are three methods for calculating vaccine needs:

- Estimates based on the target population
- Estimates based on previous consumption (historic usage)
- Estimates based on the size of immunisation sessions (This method is more suitable for planning at lower levels such as the district and health-facility level

The accuracy of estimates will depend on the quality of the data used and the knowledge of the person doing the calculations

3.4.1 Estimates 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 in the area (e.g. number of pregnant women and children)
- Details of vaccines included in the national schedule; such as the number of doses and the number of doses per vial
- The wastage multiplication factor for each vaccine and syringes.

Defining target groups
The National Programme defines the target groups for EPI. The responsibility of the vaccine manager is to indicate the operational implications of any changes that are made with respect to the target groups e.g. during the introduction of new vaccines (e.g. PCV and Rotavirus vaccines), it would be responsibility of the operations manager to set out the logistics implications such as increased need in storage, distribution and handling costs that such a decision will have. It is the responsibility of the National EPI programme to consult with the Provincial EPI coordinators/ managers before finalising policy decisions.

Identify catchment population
All health districts are now clearly defined, with population estimates, and it should be possible to identify the catchment population of each facility. Without an identified catchment population, it is not possible to measure many of the indicators upon which EPI relies. It is the responsibility of each level of service to identify and quantify its relevant catchment population.

There will always be a measure of cross-border or cross-boundary movement of the population. This, however, normally levels out with approximately the same number of people moving in as there are those moving out. If there is an extraordinary large population of people, moving in from outside the catchment area, appropriate adjustments will have to be made in the determination of the catchment area

Estimating size of target population
The size of the target population is fundamental for planning EPI operations. It is the task of the provincial or district EPI team to establish the size of the population served by each facility, both for routine services and for special programmes. Provincial information managers/officers at all levels can be of assistance for these numbers. Official publication from DHIS and District health barometer 2010/11(Health Systems Trust)

Routine vaccination
Wherever possible, use birth registration; when this is not possible, consult other authorities e.g. schools, census estimates, local tribal authority estimates, head counts and birth rates tables (current census or DHIS data extrapolation).

Supplementary immunisation Activities (SIAs) {Campaigns, mop-up, catch-up etc}
Consult other authorities e.g. schools, census estimates, local tribal authority estimates, head counts, birth rates table (current census extrapolation)

Table 3.1
EPI target population according to immunisation activity

Target Population	Routine Immunisation	NID – Polio campaigns	Measles Campaigns
Children from 0 to 12 months	X		
Children from 0 to 59 months		X	
Children from 6 to 59 months			X

Table 3.2
Rough guidelines for calculating target population

Total population of country (most recent figures)	% of total	50,270,000 million inhabitants
Children from 0 to 11 months	2.0	1 005 000
Children from 0 to 59 months	10	5, 027,000
Pregnant women	2.0	1 005 000

3.4.2 Estimates based on previous consumption (historic usage)

Estimates based on previous consumption need good data on vaccine use in the facility/district. The adoption of a stock card, which gives monthly usage data over a period of time, will facilitate this method of estimating vaccine needs.

If there is no recorded monthly stock usage, the following can be calculated if there is reliable stock management data available:

- Initial stock at the start of a given period
- Vaccines received during this period
- Stock in hand at the end of the period

If there is a record of any stock lost due to expiry, damage by heat, freezing or any other unusual occurrence (avoidable wastage), this vaccine should not be taken into consideration when calculating the quantity of vaccines needed.

An example of the method to be used for the calculation of vaccines needed using the historical data is:

Initial stock at the start of the year – doses/vials	+	Quantity received during the year – doses/vials	–	Stock in hand at the end of the year – doses/vials	–	Quantity wasted during the year – doses/vials	=	Total doses/ vials used for the year
1050		4000		1750		45		3255

Estimating vaccine requirements

For a given population the quantities of vaccine required are sensitive to the following factors:

- Number of children attending at each session daily
- Consideration of the revised Opened Multi-Dose Vial Policy
- Size of vaccine presentation used
- Wastage factor of the vaccine presentation used

3.4.3 Identify session frequency and estimate session size

- Use records to determine how often immunisation sessions were actually organized
- Check the records to see how many children attended each session
- Determine the number of doses issued and number of doses administered
- Estimate quantities and select presentation

Established fixed clinics:
Total number of doses administered in supply + reserve stock of 25% or 2 weeks consumption whichever is the greater - balance of vaccine in stock

Outreach/Mobile:
Total number of vials opened x doses per vial + reserve stock of 25% or 2 weeks consumption whichever is the greater - balance of vaccine in stock

New Clinics or those with erratic attendance
Total size of target group ÷ number of sessions in the supply period x number of doses per vaccine x wastage factor + reserve stock of 25% or 2 weeks consumption whichever is the greater

Which presentation?
Many of the vaccines are available in both single and multi-dose presentations. Some of the single dose presentations are supplied exclusively to the private sector, whereas vaccines for use in the public sector are supplied either as a single dose presentation or a multi-dose vial depending on the vaccine. In general, single dose presentations are far more costly than their multi-dose counterparts.

3.4.4. Estimating wastage

Vaccine wastage is an indication of programme cost effectiveness; it is also an invaluable indicator for clinical practice and highlights the effect of logistical decisions. For example a sudden change in wastage rates for a given vaccine at a clinic could indicate incorrect dosing of vaccine or failure to dispose of opened vials of measles vaccine. Wastage will also indicate the cost to a programme following an 'on demand' policy where vaccines are discarded before the optimum number of doses has been administered.

Vaccine wastage is of two types: **avoidable** and **non-avoidable** wastage.

The most important cause of **unavoidable wastage** is discarding of reconstituted vaccines at the end of an immunisation session. Some vaccine presentations do not give the number of doses as stated by the manufacturers.

Avoidable wastage, which can be prevented by through good vaccine management, is usually due to one or more of the following factors:

- Poor stock management resulting in oversupply of vaccines which may expire before use
- Vaccines damaged by exposure to inappropriate temperature due to failure of cold chain
- Freezing of vaccines
- Inappropriate dose
- Breakage or damage to the vials
- Not using the multi-dose vial policy properly

Wastage is calculated as follows:

$$\text{Vaccine usage (rate)} = \frac{\textit{Number of doses administered} \times 100}{\text{Number of doses issued}}$$

Vaccine wastage is the opposite of vaccine usage and is given by:

Vaccine wastage rate = *100 – vaccine usage rate.*

$$\text{Wastage (\%)} = \frac{\textit{Doses issued - doses administered} \times 100}{\text{Doses issued}}$$

Doses issued are the total number of vials opened, multiplied by the number of doses per vial;

Doses administered are obtained from the monthly report or tally sheets;

Example: Wastage calculation

Total Hep B vials issued from store	80 vials
Doses per vial	10 doses
Total doses issued	*80 x 10 = 800 doses*
Doses given	
Hep B1	220 doses
Hep B2	210 doses
Hep B3	200 doses
Total doses given	*630 doses*
Wastage	***(800-630)÷800 x 100 = 21.3%***

Note: *As a result of the MDVP policy, there may be one or more partly used opened vials of vaccine in the refrigerator, depending on the number of immunisation points in the facility. Only one vial of the same vaccine can be opened for vaccination at a immunisation point is allowable. This vaccine will be used first in subsequent vaccination sessions if MDVP allows.*

3.4.5 Wastage multiplication factor

The wastage multiplication factor is a numerical derivative used to account for the correct amount needed for immunization session, taking into account the existing wastage rate.

In vaccine forecasting the vaccine **wastage multiplication factor** is used rather than the rate. The vaccine wastage multiplication factor indicates how much additional vaccine should be ordered in order to allow for the given wastage rate.

The calculation for the wastage factor can be done in a variety of ways e.g.

Formula for Calculating Wastage Multiplication Factor (per dose)

$$\text{Wastage Multiplication factor} = \frac{100}{100 - \text{Wastage rate}}$$

For a 25% wastage rate:

$$\text{Waste multiplication factor} = \frac{100}{100 - 25}$$

$$= \frac{100}{75}$$

$$= 1.3333$$

Example 1:

If 150 doses are required and the wastage rate is 25%,
the calculation will be as below:
Number of doses required: 150
Wastage rate: 25%
Wastage Multiplication Factor: 1.33

Number of doses to be ordered: 150 X 1.33 = 200

Example 2:

If 310 doses are required and the wastage rate is 25%,
the calculation will be as below:
Number of doses required: 310
Wastage rate: 25%
Wastage Multiplication Factor: 1.33

Number of doses to be ordered: 310 X 1.33 = 412
Calculating annual estimates for EPI Vaccine

1. Determine the annual target population of children less than one year of age
2. Determine coverage required (usually 100% coverage)
3. Use the number of doses given in the EPI schedule (eg: 1 dose for BCG, 3 doses for PCV, 4 doses for Hexavalent, 2 doses for Measles, etc)
4. Calculate the Wastage Factor (WF) from the wastage rate:

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

Wastage rate is different for different vaccines, based on country/WHO estimates:

- SA wastage rate estimates:
- BCG - 80%,
- OPV - 40%,
- TT and Td - 25%,
- Measles - 55%,
- PCV, RV, Hexavalent - 5% (for single dose vials)

5. Determine the number of doses required:
   Target pop <1year x coverage x number of doses in EPI schedule x WF
6. Determine number of vials required annually:
   Number of doses required/ number of doses per vial
7. Buffer required is about 15% of annual requirements and is added to vials required (rounded off to nearest 10) Total annual vials required = Vials required annually + buffer
8. Monthly vials required = Total annual vials required /12
9. The annual vaccine estimates are then sent to the provinces in July for calculation and / or adjustment by the province for the following year. Adjustments from the provinces are usually based on estimated annual usage figures from the depot system for the year. Some province added an increase if there are cross boarder issues or influx of immigrants.
10. These annual vaccine estimates are then given to Biovac in order to secure vaccines for SA for the following year

For example 1: Annual EPI vaccines estimation for a province with a target population of under 1 year estimated at 130 000 babies, Buffer stock assumed to be 20% or 15%;

Vaccine	<1yr Target population	Expected Coverage %	No. of Doses in Schedule	No. of doses per vial	Wastage Multiplication Factor	Doses Required	Buffer needed	Annual doses needed	Annual vials needed	Rounded Off
	A	B	C	D	E	F=AxBxCxE	G=F x 0.2	H=F+G	I=H/D	J
BCG Intradermal	130 000	100%	1	20	5.00	650 000	130 000	780 000	39000	
bOPV	130 000	100%	2	20	1.82	473 200	94 640	567 840	28392	
Measles	130 000	100%	2	10	2.22	577 200	115 440	692 640	69264	
Tetanus/ Diphtheria	130 000	100%	2	10	1.33	345 800	69 160	414 960	41496	
Tetanus Toxoid	130 000	100%	3	10	1.33	518 700	103 740	622 440	62244	
Pneumococcal	130 000	100%	3	1	1.05	409 500	81 900	491 400	491400	
Rotavirus	130 000	100%	2	1	1.05	273 000	54 600	327 600	327600	
DTaP-IPV/ Hib/HBV	130 000	100%	4	1	1.05	546 000	109 200	655 200	655200	

Another Method of Calculating Doses Including Wastage

For a wastage rate of 20%
20% of 100 = 20
100 – 20 = 80
To immunise 80 children, we need 100 doses
Therefore to immunise 500 children we need?

100 X 500
80
= 625 doses of vaccine

Wastage factor = 625/500
=1.25

3.5. Estimating parenteral supplies (i.e. syringes and needles)

In addition to vaccines, EPI requires the following parenteral equipment:

2 ml syringes
5 ml syringes (for reconstitution)
18G x 1.5" [1,2 mm x 40 mm] needles (pink) [for reconstitution]
23G x 1" [0,60 mm x 25 mm] needles (blue)
29G x 0.4" (0.33mm x 8 mm) needles for measles vaccine injection
BCG syringes (fixed needle)

Estimating quantities

2ml Syringes:	*Number of injectable doses to be administered +10% less stock on hand*
5ml Syringes:	*Number of Measles and BCG vials to be used + 10% less stock on hand*
18G Needles:	*Number of BCG + Measles vials to be used + 10% less stock on hand*
23G Needles:	*Number of injectable doses, excluding Measles and BCG to be administered + 10% less stock on hand*
BCG syringes:	*Maximum number of BCG doses to be administered in one session + 10% less stock on hand*

3.6 Estimating other immunisation supplies

Estimating quantities

Cotton swabs	Total number of injections given + 10%
Immunisation cards	Total number of newborns registered + 20%
Tally sheets reports forms etc.	Based on previous consumption.

Example 2: of guide in calculating the annual estimate of vaccines and injection equipment for a district with a target population 10000 infants (using current WMF)

Vaccine	Target population	Number of doses	Doses per vial	WMF	Doses	WMF syringes	0.05 ml syringes	0.5 ml 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
BCG	10000	1	20	5	50000	1.11	11100		3330		144
OPV (oral)	10000	2	10	2	40000						
RV	10000	2	1	1.05	21000						
DTaP-IPV-Hib-HBV	10000	4	1	1.05	42000						
Hep B	10000	3	10	1.43	42900	1.11		33300		4290	376
PCV	10000	3	1	1.05	31500						
Measles	10000	2	10	2.22	44400	1.11		22200		4440	266
Diluent											
BCG	10000	1		6.66	66600						
Measles	10000	2		2.22	44400						
Total							11100	55500	3330	8730	787

The World Health Organization advocates the concept of bundling in estimating the accessories used in vaccination services. It comprises of a theoretical bundle which includes the vaccines, syringes and 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 items. "Bundling" has no physical connotation and does not imply that items must be "packaged" together.

3.7 Supplementary Immunisation Activities (SIAs)

Vaccine estimates for SIAs (campaigns and special orders) are calculated as follows:

Size of the age group (cohort) to be immunised x number of doses per child + a percentage for uncertainty in the size of the cohort + wastage (or x wastage multiplication factor) ÷ size of presentation (rounded up to the next whole number).

Example: SIA Vaccine Estimate Calculation

A = Children to be immunised 60,000
B = Uncertainty over size of cohort say 5% 3,000
C = Doses per child 1
D = Presentation (in doses) 10
E = Wastage factor 1.25
(A + B) x C = Doses needed **(G)**
(G x E)÷D = Total number of vials required **(J)**
(60,000 +3,000) x 1 = 63,000 doses
(63,000 x 1.25) ÷10 = 7875 vials

Note: Wastage for measles vaccine is considerably less in Supplementary Immunisation Activities because many children are vaccinated in each session. A 10% wastage could be considered instead of the 55% calculated in routine immunisation.

Reference should also be made to the Campaign Field Guide for SIA planning

3.8. The Revised Opened Multi-Dose Vial Policy

The revised policy applies only to vaccines which meet WHO requirements for potency and temperature stability, are packaged according to ISO standards

ISO Standard 8362-2 and contain an appropriate concentration of preservative, such as thiomersal (injectable vaccines only).

The Revised opened multi-dose vial policy states that: Opened vials of, OPV, TT, Td, Hepatitis B and vaccines may be used in subsequent immunisation sessions for a maximum of one month after opening, provided that each of the following conditions has been met:

- The expiry date has not passed
- The vaccines are stored under appropriate cold chain conditions (2-8° Celsius with temperature monitoring and recording)
- The vaccine vial septum has not been submerged in water
- Aseptic technique has been used to withdraw all doses
- The VVM (for vaccines with VVM) has not reached discard point

Opened vials of measles, BCG& yellow fever vaccines

Reconstituted vials of Measles, BCG and Yellow fever vaccines must be discarded at the end of each immunisation session or at the end of 6 hours of reconstitution, whichever comes first.

DTaP-IPV-Hib-HBV (Hexavalent) is a single dose fully liquid vaccine

All opened vials must be discarded immediately if:

- Sterile procedures have not been fully observed or
- There is even a suspicion that the opened vial has been contaminated, or
- There is a visible evidence of contamination such as a change in appearance, floating particles, etc

4. Receipt/Dispatch of Supplies

4.

Supply intervals

The supply interval determines how frequently vaccine is delivered to a particular store. The supply interval selected will influence the cost effectiveness of the programme. If it is short, it can increase the cost and create an unrealistic administrative burden, but reducing the length of the supply interval diminishes the volume of refrigeration equipment required to satisfy a given annual consumption. Too long an interval may put the vaccine at risk and results in too much vaccine being in the pipeline, especially if a sustainable power supply cannot be guaranteed.

Selecting the supply interval for clinics will depend on:

- Reliability/cost of delivery/collection
- Speed of delivery
- Reliability of suppliers (including depots and sub-depots)
- Reliability of refrigeration at the healthcare facilities
- Reliability of management at the facility
- Quantity of the vaccine stored

Supply intervals for different levels in South Africa currently are:

Provincial Depot	**Sub- depot/district**	**Clinic**
3 months	1 month	1 month

4.1 Vaccines

All Levels

- Delivery to be made to a named facility storage eg; Mthatha General Hospital Pharmacy
- Check that the delivery is sent to the correct addressee
- Check for open or damaged packing or vaccine carrier/cold box
- The shipment date and time should be checked to determine how long the package was in transit
- Verify that the cold chain has been properly maintained throughout the period of transportation as confirmed by adequate temperature-monitoring devices like cold chain monitor cards (CCM) and/or Freeze Watch indicators(FW)
- Record the contents of each shipment on an inventory log (stock record). This record should include the name of each vaccine, the number of doses for each vaccine received, the date it was received, the condition of the vaccines upon arrival, the name of the vaccine manufacturers, the lot numbers, the expiration dates for each vaccine, and any action taken as a result of a question of vaccine integrity.
- Check the quantity and type of vaccine against the invoice/delivery note;
- Sign the delivery note while mentioning any problem/discrepancy noted;
- If there are discrepancies - contact the supplier and report the problems to the cold chain manager

4.1.1 Check for proper maintenance of cold chain

Cold Chain Monitor Card

Cold chain monitor cards (CCMs) are used to record the accumulated effect of temperature over time. These cards are activated by pulling out the small tab on the left side of the indicator and shipped with vaccine consignments to measure the temperature along the vaccine's journey. This information can then be used to assess the condition of the vaccine that the CCM accompanied. (Further details on CCM are found in section 11.3)

Figure 4.1
The Cold Chain Monitor Card

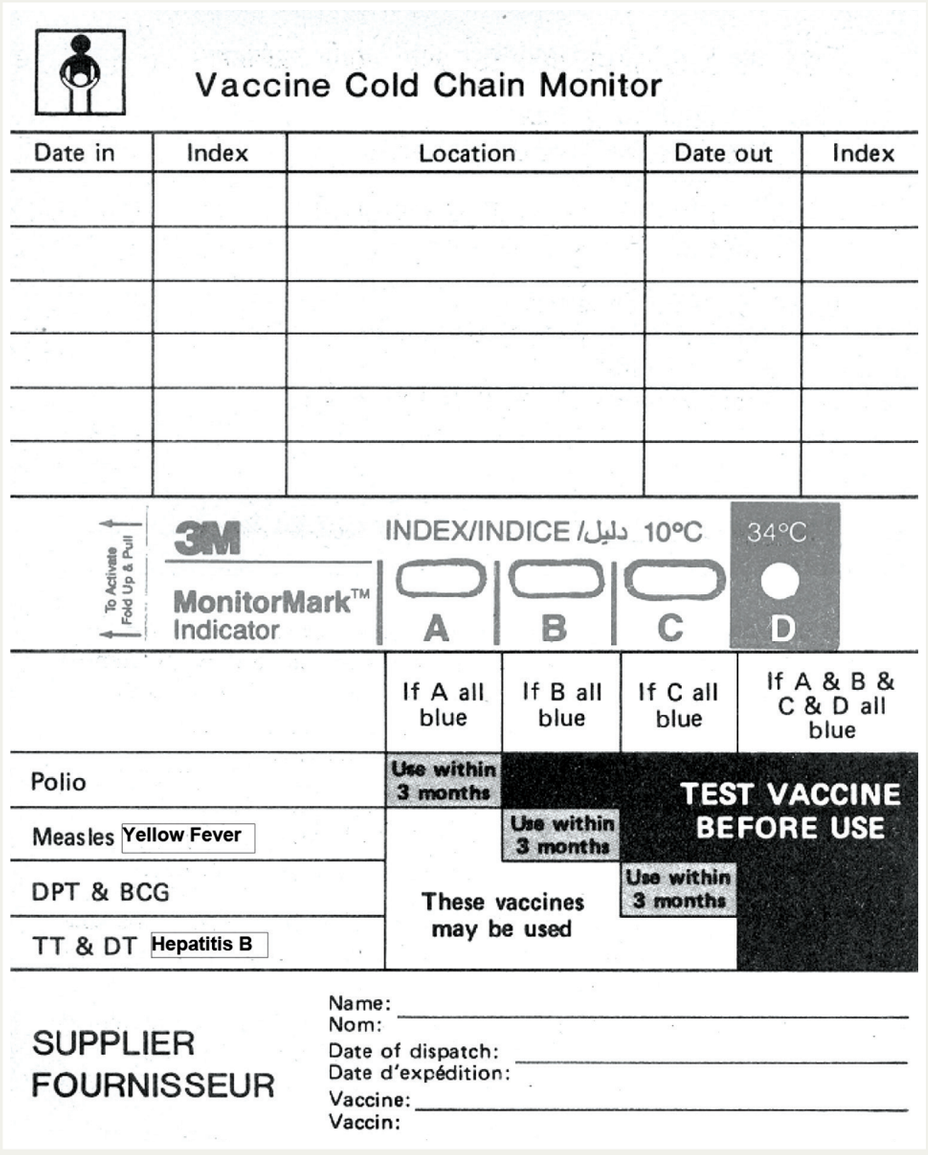


Table 4.1
Reading/interpretation of the Cold Chain Monitor Card (CCM)

Condition	Action
All white	Accept the shipment and stock normally
A window blue or partly blue or B window partly blue	Record reading on the shipping document. Accept the shipment. If OPV, check VVM indicator for potency, check VVM status of any other vaccines, otherwise use balance of vaccine shipment normally
B window blue or partly blue or C window partly blue	Record reading on the shipping document, Accept the shipment. For OPV and Measles, check the VVM, and do not use if it has reached discard point. Use all other vaccines normally. Report immediately to the supplier.
C window blue	Record reading on the shipping document, Accept the shipment, if OPV, or measles, check VVM status and use accordingly. On OPV and any other vaccines), if no VVMs, use DTaP-IPV-Hib-HBV or BCG within 3 months and use all other vaccine normally. Report immediately to the supplier.
only D window blue	Record reading on the shipping document, Accept the shipment, and use all vaccine normally. Report immediately to the supplier.
ABCD windows all blue	Record reading on the shipping document, Accept the shipment, and Check the status of the VVM on all vaccines. Do not use any vaccine unless the VVMs indicate good potency. Report immediately to the supplier.
Freeze Watch (FW) burst) -0.5ºC	Record reading on the shipping document, Accept the shipment, Do not use DTaP-IPV-Hib-HBV (Hexavalent) PCV, RV, TT, Td or Hepatitis B vaccine. Report immediately to the supplier. Remember to keep the cold chain

- Place the active cold chain monitor card/FW in the refrigerator with the vaccines received; if there are no CCMs with the shipment check the condition of the ice packs.

Condition of ice packs

Condition	Action
Ice packs frozen	Record “ice packs frozen” on the shipping document, if Hepatitis B, DTaP-IPV-Hib-HBV, Td, RV, PCV or TT is in the shipment check to see if vaccine has been frozen (Shake test) if it has been frozen, record “Vaccine frozen” on the shipping document and report to supplier, and supervisor. Do not use that vaccine. If it has not been frozen, accept the shipment and use normally.
Ice packs not frozen but cold	Record “ice packs not frozen” on the shipping document, Accept the shipment, check the VVM status and report to supplier and supervisor and use normally.
Ice packs not frozen and warm (ambient)	Record “ice packs warm/room temperature” on the shipping document, Accept the shipment, check the VVM status, and report to supplier and supervisor. Do not use vaccine unless the VVM indicates a specific vaccine is still potent.
No ice packs	Record “no ice packs” on the shipping document, Accept the shipment, and report to supplier and supervisor and do not use vaccine.

Vaccine Vial Monitor:

For any vaccine that is supplied with a Vaccine Vial Monitor (VVM), check the condition of the VVM. If it indicates that the vaccine is still potent, use the vaccine normally. If it has reached discard point and shows that there has been too much exposure to heat, report to the supplier and supervisor and do not use the vaccine. (See Section 11.3 for description of VVM)

4.1.2 Stock Recording

Record the incoming stock including date, batch number and expiry date on the stock record. If vaccine is short dated, check the remainder of the stock. If any of the vaccine cannot be used before expiry, report to the supplier and request replacement.

Short dating:

Level	Definition
National	Less than the period specified in the tender
Provincial	Less than four times the supply interval
Sub-Provincial	Less than three times the supply interval
Clinic	Less than twice the supply interval

- Place vaccines in the refrigerator, sorted by type, so that they will be removed for use in expiry date order (EEFO - Earliest Expiry First Out);
- Include sufficient diluent in the refrigerator (enough for two days) to ensure maintenance of the cold chain when reconstitution occurs;
- If vaccine cannot be used because of incorrect shipping, place the vaccine one side in the refrigerator and mark "Do Not Use" + date of receipt.
- Report any problems to your supervisor.

Provincial and sub-provincial stores may have computerised stock control systems in use. Vaccine shipments should be controlled and monitored by these systems where they exist.

4.2 Cold chain breach

The cold chain adherence is a shared responsibility of all that work with and or use vaccines. It is a shared responsibility that begins from the time the vaccine is manufactured, and ends when the vaccine is finally administered to the recipient.

A cold chain breach occurs when the temperature where vaccines are stored falls outside of the recommended +2 to +8 ºC temperature range at any point during transportation and or storage.

Common breaks in the cold chain occur through refrigeration failure, power outage, and electricity load shedding, during transportation and freezing of vaccines.

Temperature variations outside the recommended range can result in loss of efficacy to the vaccines hence it is very important that these cold chain breaks be taken seriously.

4.2.1 Cold Chain Breach Protocol Flow Chart

Immunisation facility

- Segregate all vaccines affected in the cold chain breach and immediately return to cold chain (+2 to +8ºC)
- Clearly mark the vaccines "DO NOT USE"
- Investigate the temperature the fridge/cool box has reached and the length of time the temperature was of the required range (from the temperature loggers)
- Record the type and quantity of vaccines affected in the cold chain Incident Report Form provide (Annexure 11)
- Contact the sub-district pharmacist, depot pharmacist or cold chain manager to report the cold chain breach and seek advice on vaccine efficacy and what to do next. Do not discard any vaccines prior to advice from the pharmacist/cold chain manager
- Use these vaccines first or discard, as advised by the pharmacist/cold chain manager. Discarded vaccine should be disposed of using standard medical waste procedures
- Conduct a patient recall if revaccination is deemed necessary, after consultation with facility manager/cold chain manager
- Always report all vaccine wastage to provincial cold chain manager or district pharmacist. (see vaccine wastage report forms at Annexure 12)

4.2 Other EPI supplies

All Levels

- Delivery to be made to the named person or rank
- Check delivery is sent to the correct addressee
- Check for open or damaged packing especially for syringes and needles
- Check the quantity and type against the invoice/delivery note and order
- Sign the delivery note with the problem/discrepancies noted
- If there are discrepancies - contact the supplier and report the problems

Record the incoming stock including date, batch number and expiry date (for syringes and needles) on the stock record. If syringes and needles are short dated check the remainder of the stock. If any syringes and needles cannot be used before expiry, report to the supplier and request for the replacement.

Short dating:

Level	Definition
Provincial	Less than four times the supply interval
Sub-Provincial	Less than three times the supply interval
Clinic	Less than twice the supply interval

- Place goods in store, sorted by type, so that those with expiry dates will be removed for use in expiry date order (EEFO- Earliest Expiry First Out);
- If goods are not to be used because of incorrect shipping place to one side in the store and mark "Do Not Use" + date of receipt.
- Report any problems to your supervisor.

Provincial and sub-provincial stores may have computerised stock control systems in use. EPI supplies should be controlled and monitored by these systems where they exist.

5. Storage of Supplies

5.

5.1 Stores organisation

5.1.1 Location

Most stores locations are already well established, however, additional stores will be created in the future and those that now exist may have to be moved. When choosing a location for a new store, consider the following:

- Optimal access to all sub stores
- Good access from supplying store
- Adequate level of physical infrastructure, the location must be on the road network, and be served by public utilities – water, gas, electricity etc.
- Reliability of electricity
- Availability of staff accommodation
- Reliability of communications – telephone, fax etc.
- Adequacy of administrative infrastructure (personnel, accounts etc.)
- Existing health service organisation
- Availability of qualified staff – (pharmacists/pharmacists' assistants / support staff, pickers, packers etc.)
- Security, including limited and controlled access

Once a location, which satisfies the above criteria, has been found then a specific site within that location needs to be identified.

5.1.2 Site selection

- Easy access for vehicles
- Acceptable access for staff
- Available parking
- Suitable size at ground level
- Vaccine store
- Supplementary accommodation (goods receiving, packaging storage, packing etc.)
- Room for expansion
- Secure
- Free from flooding
- Site value commensurate with value of store
- Available existing facility

5.1.3 Facilities and Size

There is a detailed guideline on sizing and design of vaccine stores printed by WHO: Guideline for establishing or improving primary and intermediate vaccine stores (Dec 2002) and also on the complete series on Effective Vaccine Store Management (Jan 2005). Details are attached in Annex 1

5.2 Stock management

The purpose of stock management systems is to obtain, store and move vaccines and other supplies to the places where they are needed in a timely fashion and at an optimum cost.

In order to maintain the quality of vaccines throughout the cold chain, it is essential to keep complete and accurate records of all stock transactions.

A stock control system comprises three steps, each of which must be performed regularly, accurately and completely. The three steps are:

1. Checking and recording details of vaccine consignments when they arrive at a storage point. These include:

- Type of vaccine
- Presentation (vial size)
- Quantity received (doses)
- Vaccine manufacturer
- Manufacturing batch or lot number or numbers (there may be more than one batch or lot in a consignment)
- Expiry date for each batch
- Ensure that quantities of vaccine and its corresponding diluents match
- Status of temperature monitoring indicators - VVM, cold chain monitor (CCM), freeze indicators and electronic data loggers on arrival of the consignment.

2. Checking details and conditions of vaccine stocks and diluents during the time they are kept in storage;

- The expiry dates of the stock should be regularly checked
- The VVMs for each batch or lot must be checked
- Any expired vials, heat-damaged vials or vials with VVMs beyond the discard point should not appear in the available stock balance. If such vaccines have to be retained for some time, e.g. until accounting or auditing procedures have been completed, they should be recorded on a separate page or card until disposal takes place

3. The same details of vaccines consignments (as on arrival) must be checked and recorded when they leave the storage point for distribution to regions, provinces, districts and eventually, the user.

A standard recording and reporting of all stock transactions should be carried out at all levels. Computerized recording is preferred when available but manual systems can be used for recording and reporting especially at the lower levels where the data to be recorded is not as huge.

Stock status should be assessed on a regular basis, preferably on a monthly basis, to ensure that there is no risk of a stock out. Simply looking up at a shelf and making a decision will definitely lead to stock outs and, consequently the inability of service providers to provide planned services. Monthly usage trends should also be monitored

5.2.1 Definitions:

Supply/Procurement Period: The frequency at which supplies are provided to facilities, or the time until the next regular order will be placed in a scheduled system. Supply period also defines the duration by which vaccines can be stored at a particular facility/store. This depends on three main factors:

- The functionality of the cold chain (availability of storage capacity, reliability of maintaining appropriate temperatures etc.)
- The performance of existing stock management (principles of distribution, batch recording, monitoring of distribution to lower levels etc.)
- The accessibility of the location (e.g. difficult-to-reach locations may request greater quantities at less frequent intervals)

Lead Time: This is the time between placing the order, and receiving the goods at the facility. Lead time varies depending on speed of deliveries, availability and reliability of transport.

The lead-time for different operational levels (national to provincial; provincial to district) is usually not more than one week, except in cases of particularly difficult accessibility. For a lead-time of less than one week, use this as the lead-time.

At the central level, however, the lead period can be up to three to four months

Average Consumption: This is the average number of units used over a given period, (usually one month) and determines how much stock should be ordered. (Normally 3 to 6 months' usage is used to calculate the average).

Maximum Stock Level: This is the target stock level, or the volume of stock needed to satisfy demand until the next order (after this one) is received.It guards against over supply that results in losing vaccines to expiration before they can be used

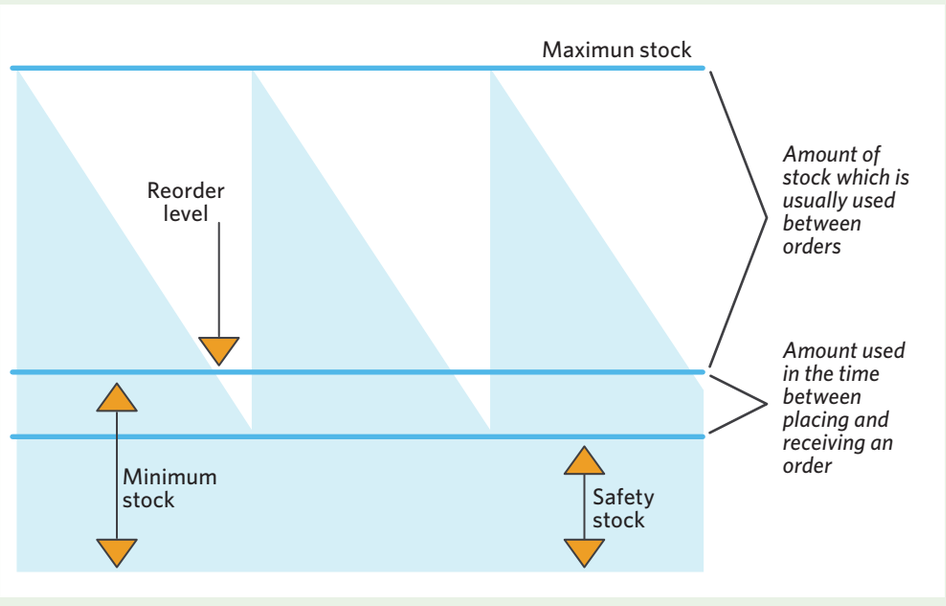
Minimum Stock level: It is the level below which stocks should never drop without having placed an order. This is the stock level that should trigger a reorder of the item. It is the amount of stock you will use in the time between placing and receiving an order plus the reserve or safety stock that is kept for emergencies and unanticipated demand or delivery delays.

Safety stock: This is the stock that should always be on hand to prevent stock outs and is usually equal to the average consumption multiplied by the average lead time (per month or per week). It serves as a buffer against major fluctuations in vaccine demands or unexpected shipment delays

Reorder Level: This is the quantity of remaining stock that triggers the ordering of the item - usually the same value as the minimum stock level.

Reorder Quantity: This is the number of units of a stock item that is ordered at each reorder interval.

Figure 5.1
Stock levels



5.2.2 Stock records

Stock recording is the means to record incoming and outgoing supplies with details of the quantity and specific characters like the expiry date, batch number of the supplies. These can be done using:

- Stock card/ledger at clinics
- A separate stock card, (at small clinics a ledger may be kept instead) or separate page in a ledger should be kept for each vaccine/diluent size and type

Stock cards should reflect date, quantity ordered, quantity received, batch/lot number, expiry date, quantity issued, running balance, signature

Example of stock cards for vaccines

Product name: ..... Card no: .....

Strength: ..... Dosage form: ..... Issues Unit: ..... Stock number: .....

or size Min/max/Reorder level: .....

RECORD OF ORDERS, RECEIPTS AND ISSUES

Date	Requisition number	Quantity ordered	Voucher number	To/From	Quantity received	Quantity issued	Stock balance	Batch number	Expiry date	Signature

TOTAL MONTHLY ISSUES

Year	April	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March	Used	Expired
20.....														
20.....														
20.....														
20.....														

Vaccine Ordering Form

Product name:..... Card no:.....

Strength:..... Dosage form:..... Issues Unit:..... Stock number:.....
or size

Min/max/Reorder level:.....

RECORD OF ORDERS, RECEIPTS AND ISSUES

Date	Requisition number	Quantity ordered	Voucher number	To/From	Quantity received	Quantity issued	Stock balance	Batch number	Expiry date	Signature

Bin cards at small stores

Bin cards have the same information as above in the clinic, plus where possible a computerised pharmaceutical control programme. Regular crosschecks are needed between stock, stock cards and computer records. Regular random stock reconciliation (audits) should be conducted quarterly

Computerised pharmaceutical stock control in provincial stores.

An approved computerised pharmaceutical programme for depot management, with, in some instances bin cards on the shelves of the warehouse/depot. Regular crosschecks between stocks, stock cards and computer records, plus regular random stock reconciliation (audits) should be conducted.

5.2.3 Calculating Minimum/Reorder and Maximum Stock Levels

Minimum stock levels are calculated by using the average consumption multiplied by the lead-time, plus the safety stock (consumption must be adjusted to correspond with the lead time).

Procurement/supply periods are normally in months or weeks, and the stock quantities in basic units.

Thus if an average 20 vials of 10-dose Hep B vaccine were used monthly, and the lead-time for delivery is 2 weeks, the following is calculated:

Minimum stock = (10 x 2) + 20 (consumption period is two weeks (20/2), lead time is two weeks, and safety stock 20)
= 40

The safety stock is lead-time multiplied by the average consumption in that period

Maximum stock levels are calculated as the minimum stock plus the procurement period multiplied by the average consumption.

Thus in a situation where the ordering is done monthly, the lead time is two weeks and the minimum stock level is calculated as 40 (see above), the following is the calculation:

Maximum stock = 40 + (1 x 20) (minimum stock is 40, average Consumption 20 vials per month and procurement period = 1 month).
= 60

The following table gives examples of **re-order levels** at different facilities using minimum/maximum data

	Provincial depot	Sub-depot	Clinic
Minimum stock	Three months	Two months	One month
Lead time	1 month	Two weeks	One week
Reorder level	4 month's stock	Ten weeks' stock	Five weeks' stock

Reorder levels can also be calculated using a reorder factor, which increases relative to the length of the procurement period. The reorder factor also includes the safety stock, but does not change in relation to the lead-time. These levels are normally higher than the minimum stock levels, giving a greater stock volume in the store, and are thus not recommended for heat sensitive items. The following factors can be used for calculating reorder levels for items such as syringes, needles etc.

Table showing reorder factors to be used for non heat sensitive pharmaceuticals and medical related items.

Supply/ Procurement period	Reorder factor for stable items[1]
1 month	3
2 months	5
3 months	7
4 months	9

1. Taken from The World Health Organisation training materials for Drug Supply Management

5.3 Expired or damaged stock

In all facilities, expired stock must be reported as avoidable wastage (See 11.3 for definition) because any stock expiring is the result of a lack of proper management of the stock. All stock damaged by heat or freezing must also be reported as avoidable wastage.

Never use a vaccine that has been stored beyond its expiry date. If vaccines are distributed correctly, each batch received should bear the **same or a later expiry date** than that of the vaccines in the refrigerator of the clinic.

If the power is out for any length of time, the following steps must be taken:

- Do not open the refrigerator until the power supply is restored unless a second working refrigerator is available;
- **Do not discard any vaccines without consultation with your vaccine coordinator or pharmacist**
- **(see attached SOP Annexture10)**

Report the following data to your supervisor:

- Duration of the power failure
- Temperature inside the refrigerator when the power is reconnected
- Quantity, by type and presentation of vaccines affected
- Expiry dates of vaccines affected
- The colour of the VVM on relevant vaccines
- Reading from the CCM if available
- Name and location of facility
- Remember that only a few, if any, of the vaccines need to be condemned if the cold chain has been interrupted. If the supervisor or pharmacist is not available immediately to take a decision on the vaccine state, keep the vaccines in the fridge at the required temperature until such a decision is taken.

If the vaccine has frozen in the refrigerator, first check the antigen. Polio, BCG and Measles vaccines can be frozen and defrosted a few times without damage to the vaccines. The other vaccines must be discarded as avoidable wastage and destroyed after recording, costing and approval by pharmaceutical services (see protocol below).

In general, more damage is done to vaccines through freezing than from limited exposure to heat.

5.3.1 Protocol for the disposal of condemned/discarded vaccines

All vaccines have a monetary value, and need to be handled correctly according to the Public Finance Management Act (Act 1 of 1999 as amended by Act 29 of 1999), and the Medicines and Related Substances Act (Act 90 of 1997).

Vaccines that expire in facility fridges, or have vaccine vial monitors (VVMs) that have reached discard point **may not be thrown away without receiving authorization from Pharmaceutical Services** in the District/Province.

Pharmaceutical services are the custodians of medicines, and have strict procedures to follow in the disposal and destruction of medicines, including vaccines.

If health care providers find expired/spoiled vaccines in the fridges, the following procedure must be followed:

1. Do not remove the vaccines from the fridge – isolate them from the vaccines that are still in date
2. Enter the information on the type and quantity of expired/spoiled vaccines on to the vaccine stock card
3. Contact the district/regional pharmacist for advice on how to proceed (provinces might differ in procedures for the removal of expired stock)
4. If you are unable to contact the district/regional pharmacist, contact the vaccine coordinator in your province, or ask your supervisor to do this for you

If the power to your fridge (electrical/gas) has been interrupted for any length of time and you did not remove the vaccines to another fridge/cold box in accordance with a contingency plan, the same steps as above must be repeated. In this case, the pharmacist will examine the vaccines to determine which of these may still be safely used in the EPI programme.

Vaccines that have been opened or reconstituted and thus issued from the stock card do not need to follow the above steps, but may be destroyed along with the other sharps waste. These vaccines include all of those that may not be used after a six-hour session, or those vaccines that have been in use for 30 days according to the MDVP

Remember, vaccines are funded from taxes collected by SA. Receiver of Revenue, and we all contribute to those taxes.

5.3.2 Shake Test

Adsorbed vaccines (Td, TT, HepB, DTaP-IPV-Hib-HBV) alter their physical appearance after freezing due to morphological changes caused by freezing on the vaccine adjuvant (Aluminium). The physical changes induced by freezing provide the basis for shake test which is useful to determine whether the adsorbed vaccine has been exposed to freezing. The shake test is predictive of loss of potency for adsorbed vaccines

After freezing, the vaccine is no longer a uniform cloudy liquid, but tends to form flakes that gradually settle to the bottom after the vial has been shaken. Sedimentation occurs faster in a vaccine vial that has been frozen than in a vaccine vial from the same manufacturer that has never been frozen.

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

Test procedure:

1. Prepare a frozen control sample:
Take a vial of vaccine of the same type and batch number as the vaccine you want to test, and made by the same manufacturer. Freeze the vial at -20°C until the contents are solid, and then let it thaw. This vial is the control sample. Clearly mark the vial as "Control" so that it cannot later be used by mistake.

2. Choose a test sample:
Take a vial of vaccine from the same batch that you suspect has been frozen. This is the test sample.

3. Shake the control and test samples:
Hold the control sample and the test sample together in one hand and shake vigorously for 10 15 seconds.

4. Allow to rest:
Leave both vials to rest.

Compare the vials:
View both vials against the light to compare the sedimentation rate. If the test sample shows a much slower sedimentation rate than the control sample, the test sample is probably potent and may be used. If the sedimentation rate is similar and the test sample contains flakes, the vial under test has probably been damaged by freezing and should not be used. Note that some vials have large labels which conceal the vial contents. This makes it difficult to see the sedimentation process. In such cases, turn the sample and reference vials upside down and observe sedimentation taking place in the neck of the vial.

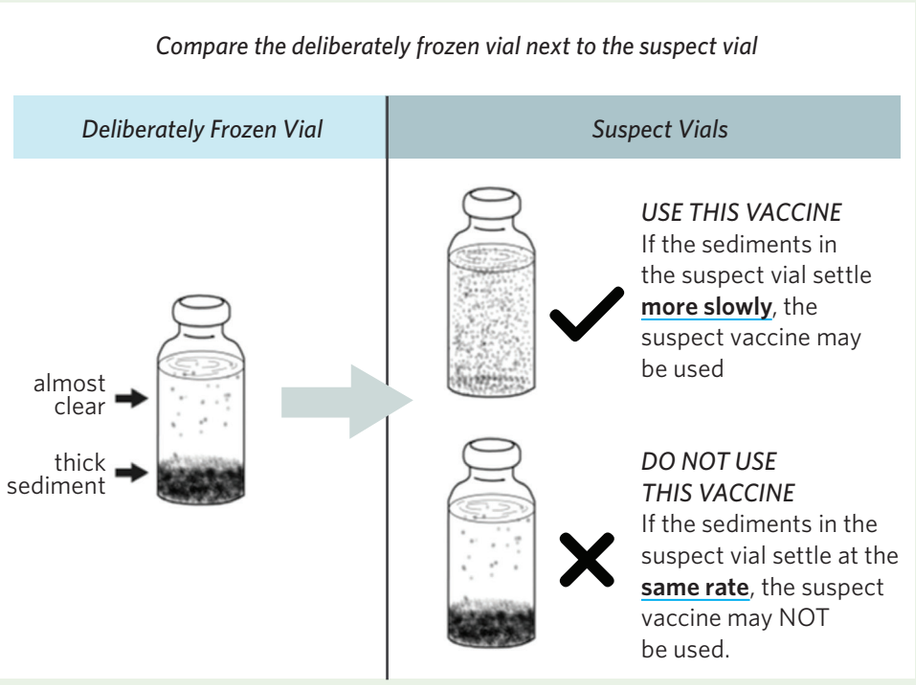


Figure 5.2
The shake test

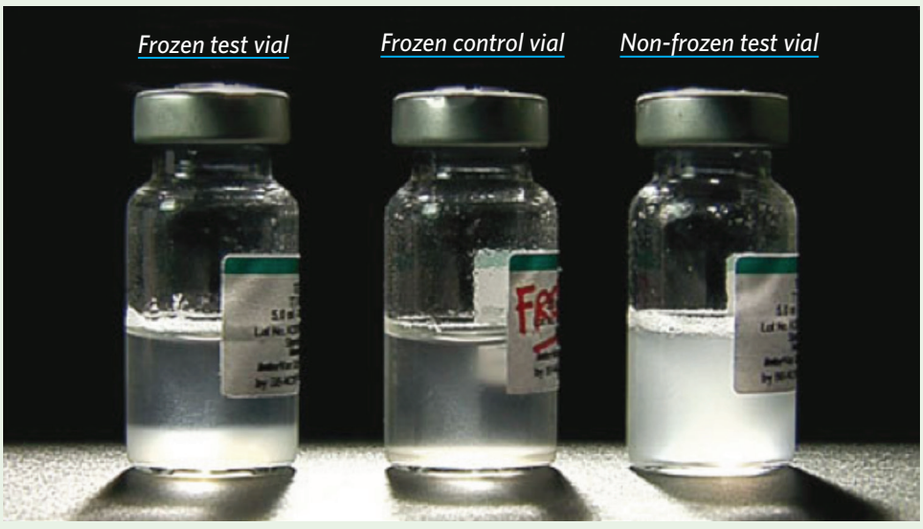


Figure 5.3
The shake test

Subsequent action:

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

5.3.3 Guidelines for discarding vaccines

(See also section 10.3.1)

Final disposal/destruction of condemned vaccines

The pharmaceutical services are responsible for ensuring that condemned vaccines are correctly destroyed (see above). This might differ slightly between provinces so provincial policies and procedures should be followed.

Empty and partly used vials

- SABS 0248:1993 defines empty vials as "clinical glass" (sharps waste) whereas expired and partly used vials are defined under "pharmaceutical waste" as biologicals (9.3.4.2). Disposal of the latter is governed by clause 7 for infectious non-anatomical waste.
- These must be incinerated and can be placed in sharps container. If no incineration is available they should be packed in a closed container colour coded black or green and marked "Partly used vaccine for destruction." and returned to the pharmaceutical depot and removed for incineration.

6. Storage of vaccines and other supplies

6.

6.1 Storage temperature

All vaccines are sensitive biological substances and lose their potency, i.e. their ability to give protection against disease, with time. The rate of loss increases as vaccines are exposed to higher or freezing temperatures. In order to maintain their quality, vaccines must be continuously stored at the appropriate temperature from the time they are manufactured until the moment of use. Different vaccines require different storage conditions. What is correct for one vaccine may be dangerous for another. It is therefore vital to know the correct storage conditions for each vaccine.

Diluents are specific to their vaccines and hence diluents are not interchangeable. For example, a diluent made for measles vaccine must not be used for reconstituting BCG, yellow fever or any other type of vaccine. Moreover, diluent made by one manufacturer for use with a certain vaccine cannot be used for reconstituting the same type of vaccine produced by another manufacturer.

6.2 Recommended storage conditions of vaccines

At different levels of cold chain

Provincial Store	Sub-Provincial Store	Clinic
Polio vaccines should be stored frozen (-20°C), while all other vaccines must be stored between 2°C and 8°C. Diluents can be stored in close proximity to the refrigerators, they should be kept cool but do not need to be refrigerated.	Polio vaccines should be stored frozen (-20°C), while all other vaccines must be stored between 2°C and 8°C. Diluents can be stored in close proximity to the refrigerators, they should be kept cool but do not need to be refrigerated.	All vaccines and sufficient diluent for at least one week should be stored in the refrigerator between 2°C and 8°C.

During distribution all vaccines must be transported in insulated containers at a temperature between 2ºC and 8ºC. Those vaccines that are normally stored frozen may be refrozen after transportation.

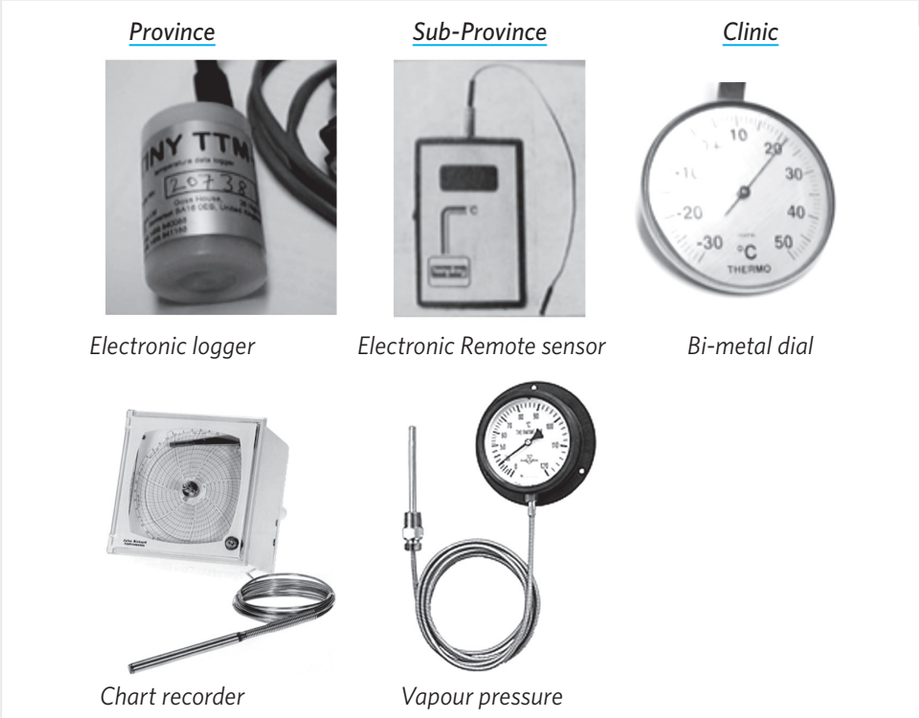
6.3 Temperature monitoring

	Provincial Store	Sub-Provincial Store	Clinic
Equipment	Use either chart recorders, or electronic recorders to continuously record the temperature in refrigerators, freezers or cold rooms.	Use either vapour pressure remote thermometers, or electronic remote thermometers which allow readings to be taken without opening the refrigerator/freezer	Use either a WHO approved metal dial thermometer or a WHO. approved fridge tags Do not use a min/max thermometer. Thermometer to be hung from the middle shelf of the refrigerator
Use	Continuous. The records from such devices should be retained for a period of 3 years	Read twice daily, first thing in the morning and last thing in the evening, on a working day. Keep a separate chart for each appliance (See Appendix 3). Charts to be kept for six months	Read twice daily, first thing in the morning and last thing in the evening on a working day. Keep a separate chart for each appliance (See Appendix 3). Charts to be kept for six months

6.4 Temperature Monitoring Equipment

The temperature recording devices recommended for monitoring the temperatures within vaccine storage units are devices that provide continuous recordings that are properly monitored. These types of devices are preferred because they provide an indication of the length of time a storage compartment has been operating outside recommended temperature ranges when a cold chain break occurs.

Figure 6.1
Examples of temperature monitoring devices



The **Log Tag**® TRID30-7 is a temperature recorder features a display together with a data logging function storing up to 7770 temperature readings. Statistical temperature and duration readings for up to 30 days can be reviewed on the display. It can be used at all levels and during distribution of vaccines.

Fridge tag: is a temperature indicator for refrigerators that shows exposures to temperatures beyond assigned alarm settings. As long as the temperature is within the allowed range, the OK sign is shown on the display. If the indicator is exposed to an out-of-range temperature the ALARM sign appears on the display. The device shows the actual temperature, all alarm violations over the previous 30 days (on a rolling basis), the daily minimum and maximum temperature of the last 30 days, and the time duration of any violation.

Log Tag®
TRID30-7

Fridge tag

Fluid-filled biosafe liquid thermometers, bi-metal stem thermometers, and household mercury thermometers are **NOT** recommended for monitoring temperatures

Temperature monitoring device Placement

The temperature monitoring device should be placed in the center of the compartment away from the coils, walls, door, floor, and fan, and the temperature probe should be placed in the vaccine box. In the refrigerator compartment, the device should be placed on the middle shelf adjacent to the vaccine. In the freezer, the device should be placed on a box (or other item) adjacent to the vaccine so that it is in the middle of the compartment, not on the floor of the freezer.

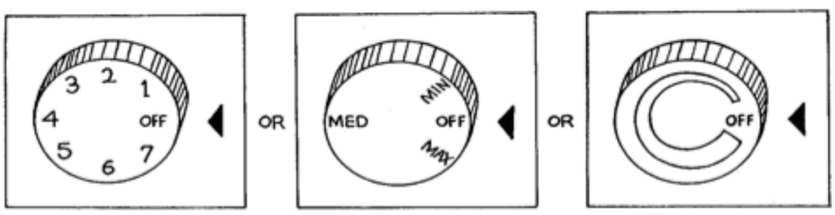
Temperature monitoring device should be checked periodically to ensure that:

- Temperature measurement is accurate
- Batteries are functioning. Maintain and change batteries as recommended by the manufacturer, keeping in mind warranty requirements.
- Cables or probes are not damaged.

Temperature management Refrigerator too cold

If the temperature in the refrigerator is too cold adjust the thermostat to a lower setting, this will reduce the amount of cooling and thus allow the refrigerator to become warmer.

Figure 6.2
Examples of thermostat dials



Numbers *Max./min* *'Snail'*

Higher number, Maximum, or widest part of the snail = **coldest**

Lower number, Minimum or narrowest part of the snail = **warmest**

Refrigerator too warm

If the temperature in the refrigerator is too warm, adjust the thermostat to a **higher** setting and this will increase the amount of cooling and thus allow the refrigerator to become cooler.

6.4.1 Stop Watch

In addition to the thermometer the refrigerator at clinic level may be supplied with the Freeze Watch or Stop Watch. Stop Watch combines the CCM indicator with the Freeze Watch and is used to monitor conditions in a refrigerator over a time.

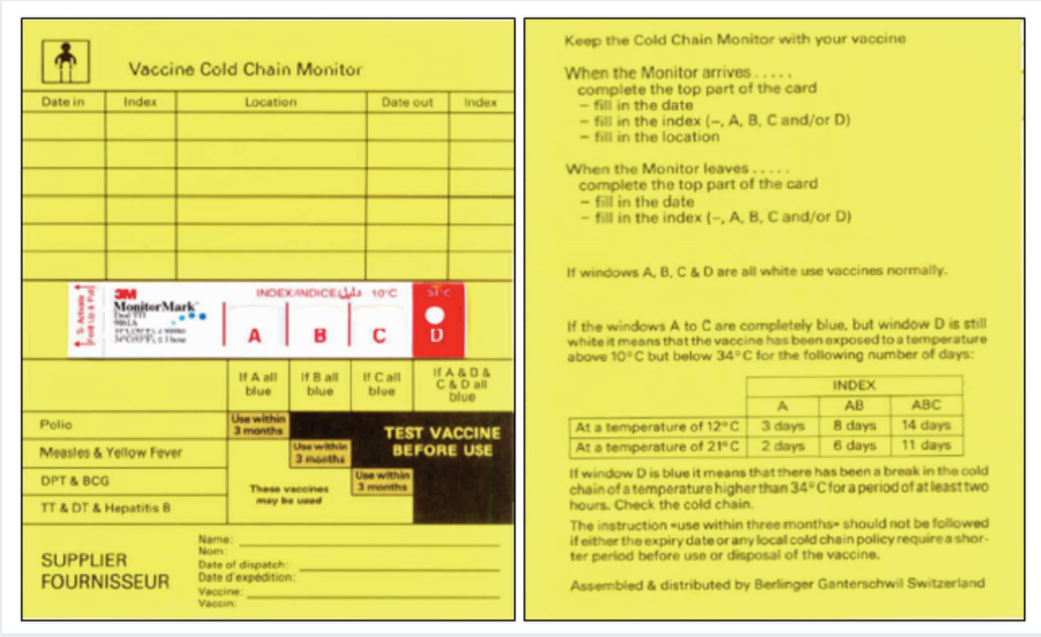
On the back of the Stop Watch there is space to record the reading from the indicators and the date. These should be filled out monthly by the supervisor each time he or she visits the clinic. When the space available is full the Stop Watch should be replaced and the old one returned to the person responsible for operations management for analysis. If the Freeze Watch is broken the Stop Watch should be replaced at once.

Figure 6.3:
The Stop Watch

6.4.2 Cold Chain Monitor Card

Cold chain monitors (CCMs) are used to record the accumulated effect of temperature over time. These cards are activated and shipped with vaccine consignments and measure the temperature along the vaccine's journey. This information can then be used to assess the condition of the vaccine.

Figure 6.4
The Cold Chain Monitor



CCMs should be included in all shipments of vaccine from the primary supplier to the Provincial depot and from the Provincial depot to each sub-depot at the rate of one CCM per 2,000 doses of vaccine. The CCM must be kept with the vaccine that it accompanies, at all times. At each stage of the cold chain, the data indicated must be completed so that at any point in the cold chain it is possible to see how much exposure the vaccines have gone through and where did it occur. This information may then be used by a supervisor should there be a problem with the vaccine.

The CCM should be:

- Stored refrigerated with the vaccines
- Included in subsequent selected shipments to the next level
- Kept in the refrigerator of the clinic/health centre. The final date should be entered when the vaccine that the CCM accompanied is finished.

For use on outreach clinics, the CCM may be taken with the last part of the consignment that it accompanied. In this way the CCM will monitor the worst condition to which some of the vaccine was exposed. If a CCM is taken on outreach it should not be returned to the refrigerator, but have the last date and reading recorded and returned to the supervisor.

The completed CCMs must be collected by the clinic/health centre supervisor and returned to the cold chain operations manager for interpretation and evaluation.

Information should be forwarded to the national cold chain operations manager on a regular basis for co-ordination and monitoring nationally.

6.4.3 Electronic freeze indicators

Electronic freeze indicators: These are small digital devices that are placed with freeze-sensitive vaccines during transport or storage. The devices have a visual indicator that shows whether the vaccine has been exposed to freezing temperatures. Once the alarm indicator is triggered, the device is no longer usable and should be discarded. Otherwise the device can be used until the built-in battery expires.

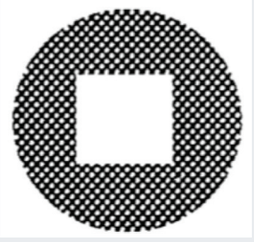
Figure 8
Electronic freeze indicators

Freeze Alert™

Q-Tag® Quad

6.4.4 Vaccine Vial Monitor (VVM)

Figure 6.6
VVM



VVMs (Figure 9) are attached to all OPV, BCG and Measles and will be attached to most vaccines sometime in the future. A vaccine vial monitor (VVM) is a label containing a heat-sensitive material that is placed on a vaccine vial to register cumulative heat exposure over time.

The combined effects of time and temperature cause the inner square of the VVM to darken gradually and irreversibly.

The rate of colour change increases with temperature.

The VVM does not directly measure vaccine potency but it gives information about the main factor that affects potency: heat exposure over a period of time. **The VVM does not register information about freezing**, a factor that may also contribute to vaccine degradation.

The VVM is a circle with a small square inside it. It is printed on a product label or attached to the cap of a vaccine vial or tube or to the neck of an ampoule.

The **inner square** of the VVM is made of heat-sensitive material that is light in colour initially and **becomes darker** when exposed to heat.

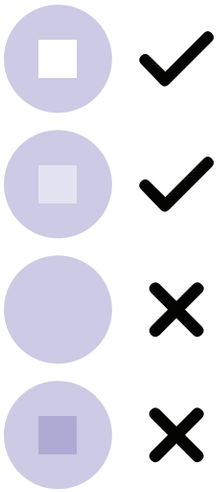
Note: The inner square is never white in colour, but has a bluish tinge.

The inner square is initially lighter in colour than the outer circle. It remains so until the temperature and/or the duration of heat reaches a level that is likely to degrade the vaccine beyond the acceptable limit. (Stage 1 and Stage 2)

At the discard point the inner square is of the same colour as that of the outer circle. (Stage 3)This indicates that the vial has been exposed to an unacceptable level of heat and that the vaccine may have degraded beyond the acceptable limit. The inner

square continues to darken as heat exposure continues, until it is much darker than the outer circle. If the inner square becomes as dark as or darker than the outer circle the vial must be discarded. (Stage4)

Figure 6.7
llustrates the VVM readings



The inner square is lighter than the outer circle. If the expiry date has not passes, **USE** the vaccine.

As time passes the inner square is still lighter than the outer circle. If the expiry date has not passed, **USE** the vaccine.

Discard point:
the colour of the inner square matches that of the outer circle. **DO NOT** use the vaccine.

Beyond the discard point:
inner square is darker than the outer circle.
DO NOT use the vaccine.

There are four types of VVM for vaccines of differing heat stability. Some vaccines are more sensitive to heat than others. The commonly used EPI vaccines can be ranked according to their sensitivity to heat as follows.

Figure 6.8
Heat Stability of Vaccines

Most sensitive to heat → **Least sensitive to heat**

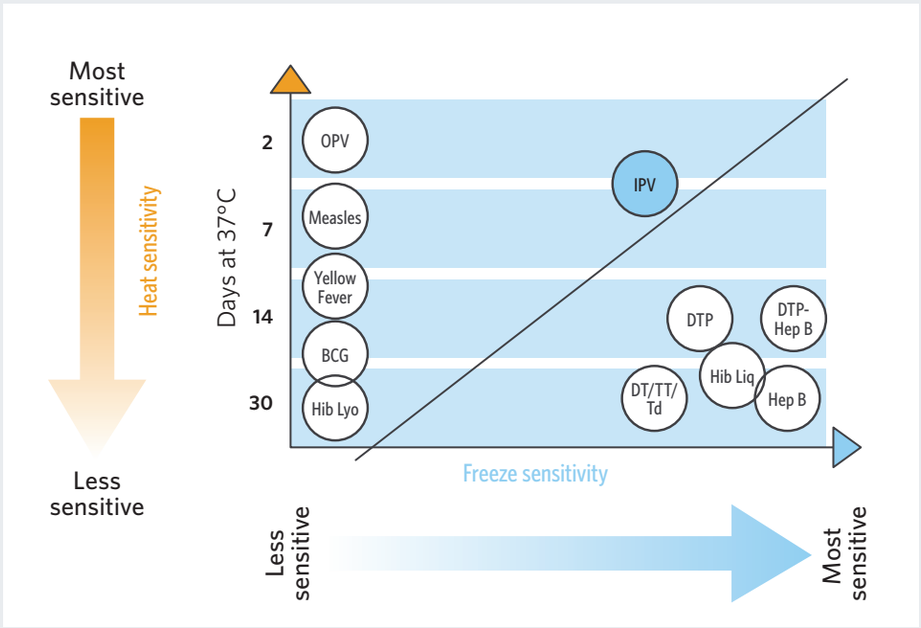
OPV, Measles, MMR, DTaP-IPV-Hib-HBV, BCG, PCV, Td, TT,HepB

The table below shows the VVM reaction rates by category of heat stability

Vaccine Category	Number of days to discard point at +37°C	Number of days to discard point at +25°C	Time to discard point at +5°C
VVM 2 Least stable	2	N/A	225 days
VVM 7 Moderate Stability	7	45	> 2 years
VVM 14 Medium stability	14	90	> 3 years
VVM 30 High stability	30	193	> 4 years

The reactions of VVMs vary in accordance with the category of vaccine to which they are assigned. There are 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. VVM2, which is assigned to OPV, the most heat-sensitive vaccine, reaches its endpoint in 48 hours at 37°C; VVM30 on hepatitis B vaccine, one of the most heat-stable vaccines, takes 30 days to reach its end-point at this temperature. However, vaccines made by different manufacturers may have different heat stability characteristics and may therefore be assigned to different categories by WHO. Manufacturer X's BCG might use a VVM30 while manufacturer Y's BCG may use VVM14.

Fig 6.9
VVM types and their relationship to temperature sensitivity of EPI vaccines



6.5 Arranging vaccines correctly in refrigerators

Correct packing of vaccines and diluent in the refrigerator is vital if they are to be kept at safe temperatures. Most refrigerators used for vaccine storage in South Africa are domestic and not designed for storing vaccines. It should be the objective of every Authority to replace equipment used for the storage of heat sensitive products with equipment specifically designed for this purpose.

The vaccines should be arranged in such a way as to facilitate air circulation and the reading of their identification as well as expiry date. Hence, vaccines whose expiry date is closest will be used first ('Earliest expiry, first out' [EEFO] principle). Vaccines whose use-by date has passed (expired) should not be administered, but put aside for destruction as per Treasury instructions.

Unused vials brought back from an immunisation session should be marked and arranged separately. They must be used first.

Open the refrigerator only in case of necessity. Have a clear idea of what you want to take out before you open the refrigerator, and do so quickly in order not to leave the refrigerator open for too long.

6.5.1 Vertical refrigerators

- The OPV, Measles BCG and Yellow fever (private sector) vials should be arranged on the coldest shelves, close to the freezing section/evaporator plate.
- The DTaP-IPV//Hib, TT, Td, RV and PCV vials will be kept on the middle shelf away from the freezing compartment. Diluents for BCG, Measles and YF will also be arranged near the DTaP-IPV//Hib and TT vials.
- Ice packs will always be kept on the lowest shelf before being placed in the freezing compartment. These can also be used as 'cold packs'.

6.5.2 Chest refrigerators:

- The vaccines should always be arranged in the baskets provided for that purpose.
- A row of ice packs should always be kept at the bottom of the refrigerator before being placed in the freezing compartment. These will help to prevent vaccines in the fridge from freezing and can also be used as 'cold packs'.
- The OPV, BCG and measles vials will be packed in the lower section of the refrigerator compartment on top of the ice packs.
- The DTaP-IPV-Hib-HBV, TT, Td, RV and PCV vials will be arranged in the upper basket, so as to keep them away from the bottom where they may be exposed to negative temperatures. The diluents for BCG and Measles will also be packed near the DTaP-IPV-Hib-HBV and TT vials.

6.6 Summary- vaccine storage principles

Vaccines must be kept at the designated temperature.

- Vaccines must not be kept:
  - *In the door compartments of domestic refrigerators*
  - *In the salad trays at the bottom of the refrigerator*
  - *In such a way that they can come into contact with the evaporator plate i.e. not close to the back or the top of the main refrigeration compartment*

- Vaccines must not be stored for longer than the specified storage period
- Vaccines must be stored in such a way that they cannot be confused with other heat sensitive pharmaceuticals. Every year, somewhere in the world there are fatalities because drugs have been mistaken for vaccine, for example insulin has been mistaken for DPT
- Diluent must be at the same temperature as the vaccine at the point of use
- Only the designated diluent may be used for specific vaccines
- Overstocking of vaccines will place all vaccines at risk as it will limit air circulation making it difficult to achieve consistent, stable air condition throughout the refrigerator.

A very useful 'tip' to remember which vaccines should not be frozen is to look for the '**T**' in the name of these vaccines.

Example: **T**d, D**T**aP-IPV-Hib-HBV, **TT**, hepa**T**i**T**is B, Ro**T**a Vaccine and conjuga**T**ed PCV, and even diluen**T**.

Table 6.1
Recommended temperatures for storing vaccines

<table>
<tr><th rowspan="2">Vaccines</th><th rowspan="2">Depot</th><th colspan="2">Sub-depot</th><th rowspan="2">Fixed Clinic</th><th rowspan="2">Mobile Clinic</th></tr>
<tr><th>Province</th><th>District</th></tr>
<tr><td></td><td>6 months</td><td>3 months</td><td>1 month</td><td>1 month</td><td>Daily use</td></tr>
<tr><td>OPV</td><td colspan="2">-15°C to -25°C</td><td colspan="3" rowspan="3">+2°C to +8°C
All vaccines are recommended to be stored at +2°C to +8°C</td></tr>
<tr><td>BCG</td><td colspan="2" rowspan="2">WHO no longer recommends that freeze-dried vaccines be stored at –20°C. Storing them at –20°C is not harmful but it is unnecessary. Instead, these vaccines should be kept in refrigeration and transported at +2° to +8°C.</td></tr>
<tr><td>Measles</td></tr>
<tr><td>HepB</td><td colspan="2" rowspan="6">+2°C to +8°C
These vaccines are freeze sensitive and must never be frozen</td><td colspan="3" rowspan="6"></td></tr>
<tr><td>DTaP-IPV-Hib-HBV</td></tr>
<tr><td>TT</td></tr>
<tr><td>Td</td></tr>
<tr><td>RV</td></tr>
<tr><td>PCV</td></tr>
</table>

Diluent vials must NEVER be frozen. When the manufacturer supplies a freeze-dried vaccine packed together with its diluent, ALWAYS store the product at between +2°C and +8°C. Where space permits, diluents supplied separately from the vaccine may safely be stored in the cold chain at between +2°C to +8°C

In the course of the 12-month evaluation period no more than one percent of vaccine should have been damaged during storage at the primary store.

NOTE: *Some vaccines are very sensitive to light and their exposure to ultraviolet light causes loss of potency. BCG, measles, 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.*

6.7 Estimating the volume requirement for vaccines

It is important to estimate the size or the volume required to store vaccines to decide whether the available storage capacity is sufficient or not. To do that it is essential to know

- The number of doses of vaccine required,
- The formulation of the vaccine (doses/vial),
- The maximum packed volume per dose and
- The temperature ranges the vaccine need to be stored (+2°C to+8°C).

The table below can be used as a general guideline to calculate the amount of space required at provincial and facility level (WHO publication- Vaccine volume calculator).

Table 6.2
vaccine volume estimation

Vaccine	Doses/ vial	Max packed volume		Annual vaccine doses required	Quarterly vaccine doses needed	Total* storage volume (quarterly in cm3)	Storage volume required by temperature range**	
		Vaccine	Diluent				-15°C to -25°C at the depot	+2°C to +8°C
A	B	C	D	E	F =E/4	G = (C+D)*F	H	I
BCG	20	1.2	0.7				=C*F	D*F
OPV	20	1						=C*F
RV	1	43.3						=C*F
DTaP-IPV-Hib-HBV	Pre-filled	107.4						=C*F
Hep B	10	3.3						=C*F
PCV	Pre-filled	55.9						=C*F
Measles	10	3.5	4					=G
Td	10	3						=C*F
Total								

**Divide by 1000 to get storage volume in litres*
***At the clinic level all vaccines (including OPV) are stored at (+2°C to+8°C)*

6.8 Estimating storage volume for Parenteral Supplies

6.8.1 Syringes and needles

100 x 2ml syringes and needles have a volume of 5 Litres V2=(50ml per syringe)

60 x 5ml syringes and needles have a volume of 5 Litres V5=(84ml per syringe)

(8.4ml per 5ml syringe assuming 1 x 5ml syringe per 10 doses of reconstituted vaccine)

Number of newborn children (NBC) to be immunised in a period (N) x number of doses of injectable vaccine in the schedule (D) x Coverage (C) x volume of syringe.

Example: Estimating Syringe and needle storage volume

Newborns: N = 50
Doses D = 7
Coverage C = 70%
Volume (2 mL syringe)V2=0.05Lt.
Volume (5 mL syringe)V5=0.084Lt
50 x 7 x 70% x (0.05+0.0084) =14.3Lt. Gross volume.

Where required quantities of syringes are known, that quantity may be multiplied by 0.05 and 0.084 (if the quantity of 5ml is not known use 0.0084 – ratio of 1:10) respectively to establish the volume of storage needed for 2ml and 5ml syringes and their accompanying needles.

The following look-up table shows the required volumes for new syringes and needles.

Look-up table to establish Required Storage Volume for New Syringes and needles

NBC/ Supply period[1]	Volume (litres) of syringes
5	2
10	4
20	8
30	12
40	16
50	20
60	25
70	29
80	33
100	41

1. Assumes 7 injections per NBC& 100% coverage.

6.8.2 Sharps containers

Allow 5Lt. per 100 used 2ml syringes and needles and 8.4Lt. per 100 used 5ml syringes and needles. If used vials are also included in the sharps container allow 20ml per used vial.

Size of Sharps Container Number of used 2ml and 5ml Syringes including needles Number of used 2ml and 5ml syringes including needles and empty vials

5Lt. 90 x 2ml + 9 x 5ml 60 x 2ml + 6 x 5ml + 6 vials

10Lt. 180 x 2ml +18 x 5ml 120 x 2ml + 12 x 5ml + 12 vials

20Lt 360 x 2ml + 36 x 5ml 240 x 2ml + 24 x 5ml + 24 vials

25Lt. 450 x 2ml +45 x 5ml 300 x 2ml +30 x 5ml + 30 vials

WHO recommends the table below as a guide to calculate the amount of space required for safe injection equipment (The unit packed volume multiplied the number required will give the volume in cm3. Divide the result by 1.000,000 to get the volume in m^3.

Safe injection equipment Unit packed volume (cm3)

0.05 ml AD syringes (only used for BCG) 35.9

0.5 ml AD syringes 60.6

2 ml reconstitution syringes 34.3

5 ml reconstitution syringes (only used for measles) 57.2

Safety Boxes (5 litres) 800

Droppers for OPV (20 dose vial) 0.9

6.8.3 Storage conditions

Syringes and needles should be stored on clean and dust free shelves in such a way that they may be used in order of their expiry date (earliest expiry, first out – EEFO).

6.8.4 Expiry dates

All expiry dates must be adhered to. If any syringes or needles reach their expiry date before they are used, sterility can no longer be guaranteed and they must be discarded for destruction.

7. Distribution of Supplies

7.1 Packing volumes

The storage volume per dose of vaccine varies. It is determined by the type of vaccine, the number of doses per vial or ampoule, the physical size of the vial or ampoule and the bulkiness of the external packaging.

7.1.1 Vaccines

Guide to calculating the net volume of vaccine used in the routine EPI in SA is shown in the table below.

Table 7.1
Vaccine volume calculator for vaccines used in routine EPI

Vaccine product	Vaccine initials	Vaccine formulation	Mode of Administration	No. of doses per vial (doses/vial)	Packed volume per dose, cm3	
					vaccines	*diluents/ drop.*
BCG vaccine	BCG	freeze-dried	ID	10	1.2	0.7
BCG vaccine	BCG	freeze-dried	ID	20	1.2	0.7
DaTP-IPV-Hib-HBV	DTP-IPV-Hib-HBV	liquid	IM	PFS	107.4	
Measles vaccine	Measles	freeze-dried	SC	10	3.5	4.0
Oral polio	OPV	liquid	Oral	20	1.0	
Pneumococcal Conjugate Vaccine 13-valent	PCV-13	liquid	IM	PFS	55.9	
Rotavirus vaccine	Rota_liq	liquid	Oral	1*	43.3	
Tetanus-diphtheria for adults	Td	liquid	IM	10	3.0	
Tetanus-diphtheria for adults	Td	liquid	IM	20	2.5	
Tetanus toxoid	TT	liquid	IM	10	3.0	
Tetanus toxoid	TT	liquid	IM	20	2.5	
Tetanus toxoid	TT	liquid	IM	Uniject	25.0	

A WHO document on the Vaccine Volume Calculator 2009 gives greater detail on the different products available. It includes spread-sheets in Excel format for use in calculating storage space needed for the introduction of new vaccines into the EPI programme. A copy of one of the spread sheets is included in Appendix 4: Vaccine storage capacity calculator and the electronic document can be downloaded for use from the WHO website at

http://www.who.int/immunisation_delivery/systems_policy/logistics/en/index4.html

7.1.2 Parenteral supplies

Product	Unit of packing	Vol./Unit Lt.
2 ml syringe	1 x 200	11,0 Lt.
Needle	1 x 100	1,0 Lt
5 ml syringe	1 x 150	8,5 Lt.
Needle	1 x 100	1,0 Lt
BCG syringe with needle	1 x 100	2,1 Lt

7.2 Packing procedures for vaccines and diluent

Vaccines should be transported in insulated containers that have been qualified to ensure they are capable of maintaining the vaccine at the correct temperatures for the necessary duration. The shipping containers used by the manufacturer to supply the vaccine, may be used to transport vaccines if they meet the criteria. Standard cold boxes and vaccine carriers are used to transport vaccines to facilities and mobile clinics.

International shipment, packing and distribution should comply with the following WHO or RSA standards.

Class A packaging
The vaccine must be packed to ensure that the warmest temperature inside the insulated package does not rise above **+8°C** in continuous outside ambient temperatures of +43°C for a period of at least 48 hours.

OPV

Class B packaging
The vaccines must be packed to ensure that the warmest temperature inside the insulated package does not rise above **+30°C** in continuous outside ambient temperatures of +43°C for a period of at least 48 hours.

Measles, BCG

Class C packaging
The warmest temperature inside the insulated package does not rise above **+30°C** in continuous outside ambient temperatures of +43°C for a period of at least 48 hours; and the coolest storage temperature of the vaccine does not fall below +2°C in continuous external temperatures of -5°C for a period of at least 48 hours.

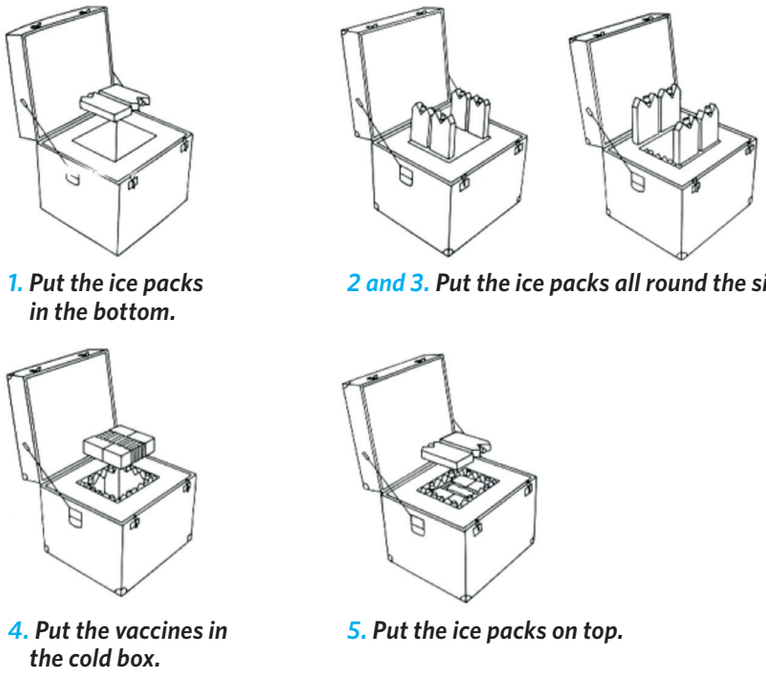
DTaP//IPV-Hib, Hep B, RV, PCV

In addition the containers must be filled with sufficient ice packs to give the container twice the length of cold life anticipated for a particular journey. For example if a courier service guarantees to deliver a package within 24 hours, that package must have a cold life of 48 hours minimum.

7.2.1 Cold Box/Transport Box Packing

Figure 7.1 illustrates the way to pack a cold box or a transport box. Transport boxes are non-returnable cold boxes. These are used by manufacturers to distribute vaccine and may be used subsequently for onward distribution.

Figure 7.1
Preparing a cold box for vaccine shipment from a depot



The following steps are illustrated in Figure 12:

1. Fully condition the ice packs. To condition the ice packs, remove frozen ice packs from the freezer and allow standing at room temperature until the ice can be heard to rattle in the ice packs. This ensures that the vaccines will not come in contact with any frozen surfaces, and freezing of vaccines will be unlikely.

2. Line the bottom, and sides of the box with conditioned icepacks.

3. If a mixed group of vaccines is to be transported, place those that can be frozen at the bottom of the box (the coldest spot).

4. Place the other vaccines on top of those mentioned in 3 above.
5. Place an activated CCM (if available) or min/max thermometer in the box in the middle of the vaccines, not in direct contact with ice packs.

6. Cover the vaccines with some more conditioned ice packs

7. If there are not enough ice packs to fully line the cold box, line the sides and cover the top only. Remember, cold air sinks, so the cold will still reach the bottom of the cold box

8. Record vaccine type(s), lot numbers, brand names, quantity, date, time, and originating facility on a packing slip on the inside of the container

9. Close the lid

10. Attach labels to the outside of the container to clearly identify the contents as being valuable, fragile, and temperature sensitive vaccines that require refrigeration immediately upon shipment arrival

To prepare a CCM for placing in the cold box take the following steps:

1. Fill in the manufacturer's/supplier's details at the bottom of the card

2. Place the inactivated CCM in the refrigerator and allow to cool for 24 hours. If this procedure is not followed, the CCM will give an inaccurate reading

3. Remove the cooled CCM and activate by pulling out the tag on the left hand side, next to the A-B-C readings

4. Place the CCM in between the vaccines and underneath the ice packs

5. CCMs that arrive from the supplier should be stored with the vaccines in the fridge and reused selectively to monitor the cold chain in transport until, the end of the line

At clinic level the CCM cards can be left in the fridge to monitor the vaccines in cases of interruption in power supply

7.2.2 Use of cold ice packs instead of frozen ice packs

Research has recently been conducted on the use of cold packs instead of frozen ice packs in transporting vaccines. The results are very encouraging, and indicate that vaccines which are prone to damage through freezing can safely be transported using cold packs. These cold packs can be stored in the refrigerators in place of the bottles of salt water on the lowest shelves of the fridge.

Table 7.2
Examples of procedures for the use of vaccine carriers, cold boxes and CCMs

Depot to Sub-depot/district	Sub-depot to Clinic	Clinic to Outreach
1. If the Sub depot is to collect: *Staff from the sub store must come with a suitable cold box or transport box plus sufficient ice packs. If the sub-depot does not have sufficient frozen ice packs they may bring unfrozen icepacks from their depot and replace these with frozen icepacks from the provincial depot.*	1. If a clinic is to collect its vaccine: *Follow the procedure for outreach. If the clinic has a problem freezing sufficient ice packs unfrozen icepacks must be brought from the clinic and replaced by frozen icepacks from the sub-depot.*	*Prepare a WHO or RSA approved vaccine carrier or cold box following the method shown in Figure 6.* *If an activated CCM is to be used place it in the carrier or box, otherwise place a thermometer in the carrier or box*
2. If the depot is delivering to the sub depot/district: *Pack a WHO or RSA approved cold box as shown in Figure 6 If an activated CCM is included, fill in the Index and date, before placing it in the cold box.*	2. If the sub-depot is delivering to the clinic: *Pack a WHO or RSA approved cold box as shown in Figure 6 If an activated CCM is included fill in the Index and date before placing it in the cold box.*	

7.3 Transport/delivery procedures

7.3.1 Transport selection, (options)

Supplier to Province	Province to Sub Province	Sub-Province to Clinic
Delivery **Courier** ***Advantages*** - Cost is known for the duration of the contract. - Responsibility for implementation is delegated - Fewer staff need by health authority - No transport need by health authority - May be more flexible ***Disadvantages*** - Loss of control - May be more expensive. - Supplier does not receive usage reports	**Delivery**	**Delivery**
Own Delivery ***Advantages*** - Fully controllable - May cost less - Can be combined with other duties - Programme monitoring is easier. - Possible to introduce a delivery circuit serving a number of locations. ***Disadvantages*** - Variable cost - Requires health authority to have more infrastructure - Vehicle availability is often problematic	**Own Delivery** ***Advantages*** - Fully controllable by supplying store - May cost less - Can be combined with other duties - Programme monitoring is easier - Possible to introduce a delivery circuit serving a number of locations ***Disadvantages*** - Requires health authority to have more infrastructure - Takes more time for supplier to supply vaccines and logistics - Vehicle availability is often problematic	**Own Delivery** ***Advantages*** - Fully controllable by supplying store - May cost less - Can be combined with other duties - Programme monitoring is easier. - Possible to introduce a delivery circuit serving a number of locations ***Disadvantages*** - Requires health authority to have more infrastructure - Takes more time for supplier to supply vaccines and logistics - Vehicle availability often problematic
Collection ***Advantages*** - Controlled by the recipient - Can be combined with other activities ***Disadvantages*** - May be more expensive. - May take more time - Requires more infrastructure at the sub-depot - Vehicle availability is often problematic	**Collection** ***Advantages*** - Controlled by the recipient - Can be combined with other activities ***Disadvantages*** - May be more expensive. - May take more time - Requires more infrastructure at the sub-depot - Vehicle availability often problematic	**Collection** ***Advantages*** - Controlled by the recipient - Can be combined with other activities ***Disadvantages*** - May be more expensive. - May take more time - Requires more infrastructure at the clinic - Vehicle availability often problematic

Note: *It is important that the shortest route to deliver vaccines with the least number of areas where the cold chain could fail should be chosen. The choice of private or state-owned transport at different levels should be made after both costing and efficiency evaluation studies have been taken into account. Contracts with privately owned concerns should include clauses for cold chain maintenance, and penalties for any break in the cold chain.*

7.3.2 Supply procedures

- Recipient store completes a provincial stock requisition stating:
- Date
- Stock item number
- Description and unit of issue
- Stock on hand
- Quantity requested
- Signature
- Authorising body (district management) approves order and signs
- Supplying store fills order and completes delivery note with date and time of despatch.

Shipments should never be sent on a Friday

7.3.3 Receipt procedures

On receipt the receiving store checks:

- Number of parcels delivered
- Quantity delivered against requisition placed
- Quantity delivered and charged against delivery note
- Condition of CCM or ice packs
- Condition of the VVMs

It is followed by:

- Placing vaccines in cold storage
- Entering quantity on the stock cards/in the stock register
- Notes any discrepancies

Discrepancies must be reported in a discrepancy report to the supplier at the earliest possible time. These include:

- Missing boxes or cartons
- Opened boxes or cartons
- Missing items
- Quantities different from those on packing list
- Incorrect items
- Damaged, expired, broken or poor quality items

8. Cold Storage and Distribution Equipment

8.

8.1 Cold Rooms

See Appendix 1: Planning of cold rooms for:

- Sizing, (option cold room or refrigerators)
- Options, selection criteria
- Care and Management including temperature monitoring
- Maintenance

8.2 Refrigerators and Freezers

8.2.1 Sizing

Please refer to table 7.1 to calculate space needed to store vaccines. The table below is a guide to calculate space required for ice pack freezing.

Estimating Storage Volumes

Provincial depot	Sub-depot/district	Clinic
Ice Pack freezing Vaccine collected:Total number of sub stores collecting in a 24 hour period x 15 = Number of litres of freezer volume required. Vaccine delivered: Total number of 20 Lt cold boxes used in a 24 hour period x 15 = Lt of ice pack freezing required.	Ice Pack freezing Vaccine collected: Total number of clinics collecting in a 24 hour period x 3 = Number of litres of freezer volume required Vaccine delivered: Total number of 10 Lt cold boxes used in a 24 hour period x 10 = Lt of ice pack freezing required.	See Table below for clinics serving up to 40,000 people. Allow 4 Lt. per vaccine carrier used for collecting vaccine plus the quantity shown in the table below for mobile activities.

Look-up Table to establish number of litres of vaccine storage required per month

Catchment Population	Volume (Lt.)
=<10,000	16
>10,000- 20,0000	32
>20,000- 30,000	48
>30,000- 40,000	64

Look-up Table to establish number of litres of freezer storage required for freezing ice packs per month for Mobile and outreach activities

	Volume (Lt.) per Number of Mobile Sessions per week[1]				
Catchment Population	1 per week	2 per week	3 per week	4 per week	5 per week
=<30,000	4	4	4	8	12

1 Based on 4 x 0.6Kg. Ice packs per vaccine carrier

Indicative sizes of cold chain equipment[2]

Provincial Depot	Sub Depot	Clinic
Increments of 300 Lt chest refrigerators + 200 Lt chest freezers up to a total of 10 each, then dedicated cold rooms	Increments of 300 Lt chest refrigerators + 200 Lt chest freezers	80 Lt refrigerator with 30 Lt of freezer capacity

2. All equipment used for storing vaccine should be either WHO or RSA approved for vaccine storage

8.2.2. Options

Using the correct freezer and/or refrigerator can help prevent loss of costly vaccines and the inadvertent administration of compromised vaccines. Freezers and refrigerators are available in many different sizes, types (e.g., stand- alone versus combination), and grades (e.g., household, commercial, and pharmaceutical). Stand-alone freezers and refrigerators without freezers are preferred because studies have demonstrated that they maintain the required temperatures better than combination units. Any freezer or refrigerator used for vaccine storage should have its own exterior door that seals tightly and properly and must also have thermostat controls. It must be able to maintain the required temperature range throughout the year. The unit should be dedicated to the storage of biologics and it must be large enough to hold the required amount of vaccine without crowding. A storage unit that is frost- free or has an automatic defrost cycle is preferred. If using a combination freezer-refrigerator unit to store vaccines, care must be taken to ensure that the freezer is not so cold that the refrigerator temperature drops below the recommended temperature range. There should be separate temperature controls (thermostats) for the freezer and refrigerator compartments.

Upright refrigerators
These are much more commonly available than chest units. They have the advantage that the vaccine is easily accessible, however they have a lower utilisation factor so will not hold as much vaccine for a given gross volume.

Where a refrigerator is to be shared between vaccines and other heat sensitive products a grossing factor of 10 must be applied and a dedicated part of the refrigerator must be marked for vaccine storage. The grossing factor (x10) will apply to all clinic refrigerators – this factor allows for air circulation and better temperature distribution throughout the fridge.

If the refrigerator is fully utilised for vaccine storage then a grossing factor of 3 may be applied. This will apply to all upright vaccine refrigerators used at sub stores.

Chest refrigerators
These are mostly used for storing larger volumes of vaccine at intermediate stores, the vaccine is less accessible but the utilisation is much greater. A grossing factor of 1, 2 may be applied to a chest refrigerator storing a single type of vaccine.

Compression Units
The compression refrigerator and freezer are much more efficient than absorption and are the type of choice wherever there is electricity.

Absorption Units
Although they are less efficient than compression, absorption units may be run on electricity, gas or paraffin and so are useful where there is no electricity, or the power supply is erratic. Some fridges can switch between electricity and gas and can be useful in rural areas where power cuts are frequent.

8.2.3 Choice of model and type

Once the need for refrigeration has been identified and the capacity required is known, the vaccine manager must select a specific model to satisfy those needs.

Vaccine specific refrigerators are always more costly to purchase than their domestic counterparts. This is due to the specifications for a longer hold-over period after a power failure than is required in the normal domestic fridge. As a result of this increased insulation, the running costs of these fridges is usually far less than the electricity costs incurred for domestic fridges.

A purpose-built vaccine refrigerator is the standard for storing large inventories of vaccines because of the following advantages:

- A digital feedback system ensures narrow tolerances with internal temperatures, thus providing an excellent temperature regulation system for vaccine storage
- Ongoing air circulation ensures that the temperature distribution is even
- A set-point temperature, within a +2°C to +8°C range, is kept
- Evaporator operates at +2°C, preventing vaccine from freezing
- Air circulation is fan forced
- Temperature recovery system is good
- Built to handle ambient temperature changes

As the price of vaccines rises, the importance of selecting high quality equipment becomes more important; to lose a fridge full of EPI vaccines as a result of a power failure over a weekend could be very costly.

8.2.4 Care and Management, including temperature monitoring

There should be one specific staff member whose task is to attend to and take care of the equipment. These functions should be included in the job description of that person.

Daily Tasks

Check and record the temperature every morning and afternoon and adjust the thermostat, if necessary. If using loggers, ensure that the device has not indicated an alarm.

Ensure that vaccines are kept in order and that they are not muddled up with other products. Apply EEFO.

Check that doors are properly sealed each time they are closed and at the end of each day.

With absorption units, check the flame of paraffin (kerosene) and with gas adjust the thermostat if necessary.

Clean and dry the cool boxes that have been used during the day.

In case of any problem, act according to the facility contingency plan.

Weekly Tasks

With gas absorption refrigerators, check that there is enough gas in the gas bottle and change, if necessary.

Monitor and analyse the trend of temperature recordings

Check for expired vaccines, vaccines with VVMs beyond use point and remove from

the stock if there are any.

Check if the freezer or refrigerator needs defrosting

Monthly Tasks
Analyse the trend on the temperature chart

Clean the inside of the refrigerator and wipe dry.

Clean the door gasket especially along the bottom edge on upright units

Check that the door is closing correctly.

Check if the freezing compartment needs defrosting and defrost if necessary (more than 10mm of ice on the evaporator)

Check and remove expired vaccines and vaccines with VVM beyond use point.

Clean the condenser coil on the back of the refrigerator and remove the dust that has accumulated around the compressor.

8.3 Cold Boxes and Vaccine Carriers

8.3.1 Sizing

Lookup table for estimating number of 2 Litre vaccine carriers required by clinics to collect vaccine

Catchment Population	Crude Birth Rate/1,000 pop.					
	10	15	20	25	30	35
	Litres of vaccine for transportation per supply period					
=<10,000	<1	1	1	2	2	2
11,000	<1	1	2	2	2	3
12,000	<1	1	2	2	3	3
13,000	<1	1	2	2	3	3
14,000	1	2	2	2	3	3
15,000	1	2	2	3	3	4
16,000	1	2	2	3	3	4
17,000	1	2	2	3	4	4
18,000	1	2	3	3	4	4
19,000	1	2	3	3	4	5
20,000	1	2	3	4	4	5
21,000	2	2	3	4	4	5
22,000	2	2	3	4	5	5
23,000	2	2	3	4	5	6
24,000	2	3	3	4	5	6
25,000	2	3	4	4	5	6
26,000	2	3	4	5	5	6
27,000	2	3	4	5	6	7
28,000	2	3	4	5	6	7
29,000	2	3	4	5	6	7
30,000	2	3	4	5	6	7

1 x 2 litre vaccine carrier

2 x 2 litre vaccine carriers

3 x 2 litre vaccine carriers

4 x 2 litre vaccine carriers or 1 x 10 litre cold box

Cells to the right of the heavy line could use cold boxes instead of vaccine carriers

8.3.2 Cold life, strength selection criteria

Cold boxes and vaccine carriers should have a cold life which is twice as long as the anticipated requirement. For example if it is expected that a vaccine carrier will need to keep vaccine for 8 hours it should have a rated cold life of 16 hours.

Long cold life (more than 5 days)	**Medium cold life (1-5 days)**	**Short cold life (<1 day)**
Vaccine specific design	Vaccine specific design or picnic box	Vaccine specific design or picnic box
High quality thick insulation	High quality, thinner insulation	Lower quality insulation or Thin high quality insulation
Large number of ice packs	Fewer ice packs	Fewer ice packs
Heavy, vehicle transported	Heavy, vehicle transported	Light hand carried
Highly durable	Less durable	If vaccine specific highly durable otherwise domestic strength with short use life
Expensive	Less expensive	Less expensive

8.3.3 Care and management

After use, cold boxes and vaccine carriers should be cleaned, dried and stored with the lids open. If there is any damage it should be repaired immediately. When cleaning the equipment, specifically check the lid gasket, because any damage to the gasket will seriously shorten the cold life.

9. Maintenance of cold chain equipment

9.

9.1 Cold Rooms,

When this equipment is purchased, check that the recommended spares are readily available, or the suppliers should be asked to offer a maintenance contract whereby they routinely service the cold rooms once a year.

9.2 Refrigerators, Freezers

Check if spare parts are readily available; if spare parts are not readily available they should be bought at the time the equipment is purchased and held in stock.

9.3 Equipment failure report

When there is equipment failure the following must be reported to the person responsible for equipment maintenance and repair:

Date of failure
Time of failure
Description of failure
Quantity of heat labile products being stored at the time, by type
Arrangements made for continued safe storage

9.4 Repair of Refrigeration Equipment

All new refrigeration equipment is manufactured with R134A, CFC free refrigerant. All old equipment was made with either R22 if it was a freezer or R12 if it was a refrigerator; these gases are not CFC free. It is vital that the repair technician is informed which type of equipment is being brought for repair and that he is equipped for repairing both systems.

Before a technician is hired to repair equipment the Authority must satisfy itself that he is qualified to repair both types of equipment and that he is equipped with two sets of equipment. Failure to use the correct equipment will result in contamination of the new cooling systems with R12 which will damage the equipment. New CFC free refrigerators are marked "CFC free" and must only be gassed with R134A, old equipment must only be gassed with R12.

9.5 Backup Generators

Facilities storing large vaccine inventories should install backup generators that automatically provide power to the storage units to maintain the recommended storage temperatures in the event of power outages.

Backup generators should be tested quarterly and should receive maintenance at least annually (check the manufacturer's specifications for test procedures and maintenance schedules). Backup generators should be of a sufficient capacity to run continuously for 72 hours if necessary. Plans should be made to ensure that an adequate supply of fuel is on hand.

10. Specimen Collection and Cold Chain

10.

To be read in conjunction with the field guide on EPI (SA) Disease Surveillance

From time to time during disease surveillance, specimens that have been collected from patients will have to be kept cold (refrigerated within a specified temperature range), or frozen. Examples of these are stool samples from acute flaccid paralysis (AFP) cases, and urine samples from suspected measles cases. These samples will also have to be sent under cold chain conditions to the laboratory for testing – the 'reverse cold chain'.

If a specimen is to be collected from a patient, the health worker should have specimen containers, a small vaccine carrier plus some frozen ice packs, that can be used for storing specimen. **Specimens must NEVER be placed in cold boxes with vaccines or other drugs being used on an outreach programme.** Remember, the specimen is potentially infectious and should be carefully handled, and labelled "contaminated".

On reaching the clinic, the **clearly labelled** (see Field guide) specimen should be sealed in a plastic bag and placed in a refrigerator **separate** from the other heat sensitive pharmaceuticals in the fridge. This specimen should be sent to the virology laboratory as soon as possible.

The vaccine carrier containing the specimen should be clearly marked with the name, address and telephone number of the contact person to whom it is being sent.

If the specimen is to be sent to the district hospital, en-route to the laboratory, it must be transported separately in a clearly marked vaccine carrier and the cold chain must be maintained.

The district hospital should follow the same storage procedures as above for the clinic.

When transporting the specimen to the laboratory, the same cold chain procedure as above must be followed.

It is essential for the specimen to reach the laboratory in a good condition so that a successful virological examination is conducted and correct diagnosis be made.

11. Records and Reporting

11.

11.1 Records to be kept at each clinic

- Catchment population – Official numbers based on latest Census and mid-year estimates of Stats SA
- Total catchment population served by the clinic
- Estimated number of new-borns / children < 1 year of age, per year (target population), estimate of surviving infants at one year
- Number of doses administered of each type of vaccine – documented according to provincial & district policy on Routine Health Information
- Number of vials used for each type of vaccine – complete the summary on the stock card/record monthly
- Number of doses per type of vaccine wasted – use the wastage form for calculations
- Number of BCG syringes in stock
- Total number of sharps boxes incinerated/destroyed
- Running balance of stock on hand – routinely

11.2 Frequency of reporting

- All facilities should report the following data once a month, via the Routine Information System – reports submitted according to provincial & district policy on Routine Health Information: (the current DHIS do not capture vaccine utilization data so routine vaccine data should come as a separate report)
  - Number of doses administered by vaccine type;
  - Number of doses of vaccine wasted – complete the vaccine wastage form.
  - Reports should be submitted by the end of the second week in the month.

A sample of monthly stock summary report is attached as Appendix 5: Monthly summary reporting format

11.3 Data analysis

11.3.1 Wastage

Avoidable wastage:

- Wastage due to breaks in the cold chain;
- Vaccines left in storage beyond the expiry date;
- Vaccines broken accidentally.

Unavoidable wastage:

- Wastage due to the immunisation policy
- Unused vaccines (that are reconstituted) having to be discarded after an immunisation session
- The physical/clinical limitations of the vaccine
- The number of doses administered per vial not equal to the stated number available per vial.

11.3.2 Monitor change

Cold Chain Monitor Cards (CCMs)

Changes in colour of the window on the cold chain monitor card must be reported to the supervisors and to the cold chain operations manager.

Any change in the colour of the window of the monitor card will have an influence on the usability of the relevant vaccine, and a decision on its use/ limited use will have to be taken by the manager.

Vaccine Vial Monitors (VVMs)

Storekeepers and staff responsible for vaccine must monitor the change in the VVMs.

If a consignment of vaccine has VVMs which indicate more change (turning grey) Stage2, they should be used before vaccines which have less exposure recorded. If the vaccine reaches its expiry date and the VVM is still valid the vaccine must still be discarded.

Any VVMs which record excessive exposure must be reported to the supervisor.

12. Management of Sharps

12.

12.1 Handling used sharps

NEVER strip the needle from a used syringe

ALWAYS place syringe and needle in a safe disposal box immediately after use

ALWAYS supervise the transport of the syringes & needles in the disposal box and maintain records of disposal and destruction

NEVER recap a used needle

The handling of used sharps should be in accordance with the SABS code 0248:1993 - "Handling and Disposal of Waste Materials within Health Care Facilities:"

SABS code 0248:1993 Section 5.2.1

"Each generator of waste shall prepare, maintain and implement a written plan to identify and handle all waste generated within the facility and shall provide a training programme for all staff to familiarise them with

a) Procedures for the segregation, collection, storage, labelling and movement of waste specified by this standard;
b) Personal hygiene, especially hand washing; and
c) The hazards of those materials to which workers may be exposed. This training shall be continuously assessed and reinforced."

SABS code 0248:1993 Section 5.2.2

"An inspection programme shall be established to ensure that the procedures specified by this standard are followed."

SABS code 0248:1993 Section 8.2 Containment

"8.2.1 Sharps and similar wastes shall be placed in sharps containers

8.2.2 The recapping of needles is not recommended. Needles shall not be clipped, bent or broken"

Once used, the syringe and needle must be placed intact in the sharps container. The **needle must not be detached** from the syringe. Needle destructors have not passed WHO tests and are not recommended for use.

12.2 Estimating volume of used sharps

12.2.1 Routine Services

(a) Estimate the number of 5 litre containers of syringes used for immunisation, using the look up table below.

Look up table for estimating the volume of used syringes and needles generated by immunisation at health facilities

Catchment Population	Number of 5 litre disposal boxes per month for 100% immunisation coverage					
	Crude Birth Rate					
	10	15	20	25	30	35
1,000-5,000	1	1	1	1	1	2
6,000-10,000	1	1	2	2	3	3
11,000-15,000	1	2	3	3	4	5
16,000-20,000	2	3	4	5	6	6
21,000-25,000	2	3	5	6	7	8
26,000-30,000	3	4	6	7	8	10

(b) Estimate the number of litres of syringes used per month for curative injections:

Number of 5 litres containers of syringes as follows:

Number of 2ml syringes used ÷ 100
Number of 5ml syringes used ÷ 60
Number of 10ml syringes used ÷ 40

(c) Add a+b to find total number of sharps containers needed for one month's disposal

The amount of time this will require for incineration can be estimated from the following table:

Incinerator Capacity kg/hour rating	Number of 5 litre boxes / hour
14	2
25	4
40	6
60	8
100	14
160	22
220	30

Example: Estimating Incineration time

A clinic serving 20,000 with a Crude Birth Rate of 20/'000 will need:

EPI	4 x 5 litre boxes, see look up table
Curative say,	8 x 5 litre boxes, 300 x 2ml + 240 x 5ml + 40 x 10ml
Total	12 x 5 litre boxes

Assuming the clinic has an incinerator with a nominal capacity 14Kg/hr. From the table this be able to burn 2 per hour so would require

12 ÷ 2= 6 hours of incineration time per month to burn the sharps.

12.2.2 SIAs (Campaigns)

The following algorithm may be used to estimate the number of litres of sharps waste which will be generated and the amount of incineration which will be needed to destroy those sharps.

A = Estimate of used syringes:
e.g. Total number of children to be immunised in a measles campaign.

B = Volume of used syringes = A x 50 ÷ 1000 = Total volume in litres.

C = Number of sharps boxes required to hold used sharps

For 5 litre boxes B÷5
For 10 litre boxes B÷10

D. To ensure correct and complete burning, incineration time must be controlled. All incinerators are rated for the number of Kilograms of waste they can burn in one hour. The table below shows how many sharps boxes per hour can be burnt for given sizes of incinerator.

Incinerator Capacity		
kg/hour rating	**Number of 5litre boxes/hour**	**Number of 10litre boxes/hour**
14	2	-
25	4	2
40	6	3
60	8	4
100	14	7
160	22	11
220	30	15

E = Total burning time in hours E=C÷D

Example: A Province plans to immunise 1,894,362 children with measles vaccine

A = 1,894,362
B = 1,894,362 x 50 ÷ 1,000 = 94,718 Litre. of sharps waste
C = 94,718 ÷ 5 = 18,944
Incinerator is rated at 220Kg per hour
D = 30
E = 18,944 ÷ 30 = 631 hours burning time

13. Contingency Plans

13.

Every vaccine store must have a contingency plan for keeping vaccine safe if the refrigeration equipment fails. It is impossible to give precise directions about how this should be done, as circumstances may vary. Whatever the circumstances, however, the following three rules apply in an emergency.

- Freeze-sensitive vaccines:
  Maintain vaccines at +2°C to +8°C.
- Freeze-dried vaccines packed with diluent:
  Maintain vaccines and diluents at +2°C to +8°C.
- Freeze-dried vaccines packed without diluent:
  Maintain vaccines at +2°C to +8°C. Store diluents at room temperature as normal.

13.1 Power failure

Provincial Depot	Sub Depot	Clinic
Emergency generator power should be installed for both refrigeration and freezing units. Guidelines on the procedure to be followed should be compiled. The power should be electronically monitored and a security alarm linked to a maintenance company who will notify the responsible person from the store. A paging system, or a cellular telephone linked system to the pharmacist on call is preferable. Proper maintenance and testing of the alarm system must be included in the guidelines. Back up cold storage and freezing facilities must be identified for any crisis. Emergency power must be automatically activated on power failure to ensure maintenance of the temperature ranges.	If the store is within a hospital, there should be an emergency generator power link to the refrigeration and freezing units. If the store is a separate unit, emergency generator power should be installed for both refrigeration and freezing units. Guidelines on the procedure to be followed at each level should be compiled. If possible, the power should be electronically monitored and linked to a maintenance company who will notify the responsible person from the store.	In clinics where power cuts are a regular occurrence, refrigeration with a long hold-over period (week end) is essential. A contingency guideline should be compiled by the clinic/health centre for the event of power failures. Possible alternative short term storage at nearby stores/businesses/ homes should be sought.

13.2 Vaccine shortages

Provincial Depot	Sub Depot	Clinic
Well managed vaccine stocks in a clinic/health centre should not result in shortages. In the event of extra stocks being needed in an emergency, the person responsible should justify the additional requirement and request the vaccine suppliers for emergency replacement. Any stock shortages should be reported to the Provincial and or National Vaccine Managers immediately.	Well managed vaccine stocks in a clinic/health centre should not result in shortages. In the event of extra stocks being needed in an emergency, the person responsible for vaccine management in the store should justify the additional requirement and request the Provincial depot for emergency replacement. Any stock shortages should be reported to the Provincial Vaccine Coordinator/ Manager immediately.	Well managed vaccine stocks in a clinic/health centre should not result in shortages. In the event of extra stocks being needed in an emergency, the person responsible for the vaccines in the clinic should justify the additional requirement and request the Sub depot for emergency replacement and explain the reason. Any stock shortages should be reported to the supervisor immediately.

13.3 Sudden demand

Provincial Depot	Sub Depot	Clinic
If there is an outbreak of an Vaccine preventable disease, report to the Provincial vaccine and EPI coordinators who will, if appropriate, authorise additional quantities of vaccine. Provincial storage capacity will be sufficient to hold such demand.	If there is an outbreak of an Vaccine preventable disease, report to the supervisor who will, if appropriate, authorise additional quantities of vaccine. If there is insufficient storage space for the extra vaccine, arrange with another cold store for temporary refrigeration. For example at a local private pharmacy or other enterprise with refrigeration.	If there is an outbreak of vaccine preventable disease, report to the supervisor who will, if appropriate, authorise additional quantities of vaccine. If there is insufficient storage space for the extra vaccine, either keep it in a cold box if there are sufficient frozen ice packs to maintain a safe temperature, or arrange with another cold store for temporary refrigeration. For example at a local private pharmacy or other enterprise with refrigeration.

14. Audit

14.

Annual audit (stock and document check) of all vaccines and consumables:

At the end of each supply period and before placing a new order (normally monthly), clinics will reconcile actual stock with stock records.

Once a year, Provincial depots and sub depots will reconcile actual stock with the recorded stock for vaccines, sharps boxes and syringes and needles. Any discrepancies must be reported and explained.

Annual audit of all cold chain equipment:

Provincial Depots

Once a year there will be an audit of all cold chain equipment to record condition thereof and indicate if replacement or repair is needed.

Districts/ sub-districts

Each district/sub-district will conduct a cold chain audit in order to establish a cold chain inventory register indicating the condition thereof and if replacement or repair is needed. Budget must be secured for replacement of old equipment. A fridge life is usually 10 years.

This inventory register must be up dated annually

Appendix 1:
Planning of cold rooms

A1

Provincial Cold Store

1. Planning cold rooms

The information in this section assumes the use of prefabricated cold rooms with twin packaged refrigeration, front mounted units. Figure A1 shows typical layouts and clearances for cold rooms ranging from 40m3 to 5m3. Figure A2 shows the layout and clearances required around refrigerators and freezers.

Specialist controls are needed so as to ensure that even temperatures are maintained throughout. One way of avoiding this complexity is to install several smaller cold rooms with shared dividing walls.

2. Sizing cold rooms

Algorithm: For each group of vaccines (-20oC and non frozen), total quantity of vaccine by type and presentation required÷supply period + reserve stock (3-6 months depending on criteria)x gross volumes of vaccine in Lt. x grossing factor for cold rooms (3)/1000 = Gross volume of cold room in M3. Details on how to calculate the size and numbers of cold rooms required at a provincial level can be done using the logistic planning tool published by WHO (http://www.who.int/immunisation_delivery/systems_policy/logistics/en/index5.html).

The rooms should be fitted with front mounted clip on cooling units. There should be two units per room, each equipped with automatic changeover.

The height of Cold rooms for vaccine storage should not be more than 2.2 metres. This height limit ensures that vaccines placed on the top shelf are accessible without the use of steps. Rooms should be planned so that they are as close to square as practicable. This minimizes the surface area of the cold room and reduces energy consumption.

Shelving should be arranged so that there is free movement of air between the vaccine packages. Vaccine packages should also be stored about 50mm away from the walls of the cold room. This helps to ensure an even temperature. Slatted shelving assists air circulation and is therefore preferable to solid shelving.

3. Planning cold store areas

Cold store areas should be laid out so that diluents and OPV droppers can be stored on easily accessible shelving, close to the cold room. The store should be kept cool (+25o C). Each vaccine manufacturer supplies diluent which is only compatible with its own vaccine. It is very important that diluents are systematically stored and are subjected to the same rigorous stock control procedures as the vaccines to which they belong. Experience shows that good control of diluent stock is more likely to be achieved if it is stored close to the vaccine.

4. Planning vaccine packing areas

Figure 3 gives a schematic layout for a typical vaccine packing area. The size of the space required will depend upon the maximum daily throughput and the number of staff employed. The packing area should connect to a direct route between the vaccine store and the vehicle loading area. It must not form part of a main circulation route because it has to be kept cool and secure. Vaccine packing involves a number of linked activities. All of these should be accommodated in the same space.

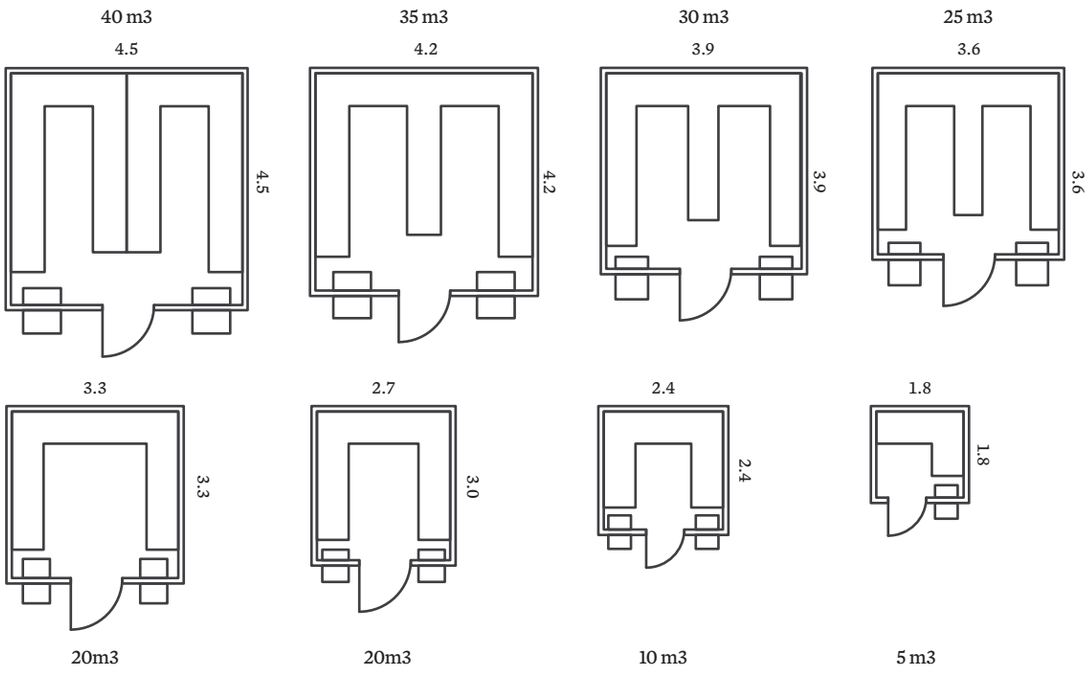
5. Calculating icepack freezing capacity

Vaccines have to be kept within the recommended temperature range during transport. Vaccines will be distributed by courier service or may be transported in vaccine transport boxes or in a refrigerated vehicle. Unless a refrigerated vehicle is used, ice pack freezing will be required.

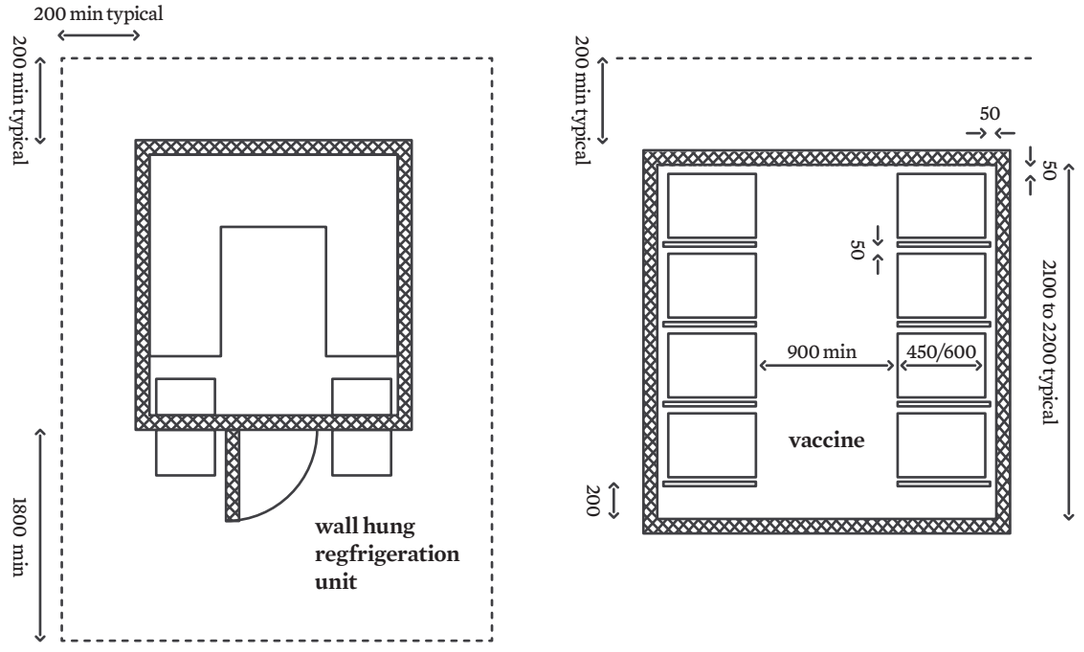
The icepack freezing capacity required depends upon the chosen vaccine distribution strategy. This brief assumes that the provinces will be supplied monthly and that the supply will be spread evenly over the month. Such a policy will maximize the merit of the national store by reducing to a minimum the size of provincial stores and keeping the quantity of vaccine in the pipeline to a minimum. To supply the required volumes of vaccine will need an ice making capacity of 100Kg per 24hrs. This can be achieved with three ice pack freezers plus one chest freezer for storage.

Figure A1:

Cold Room Planning and Dimensions



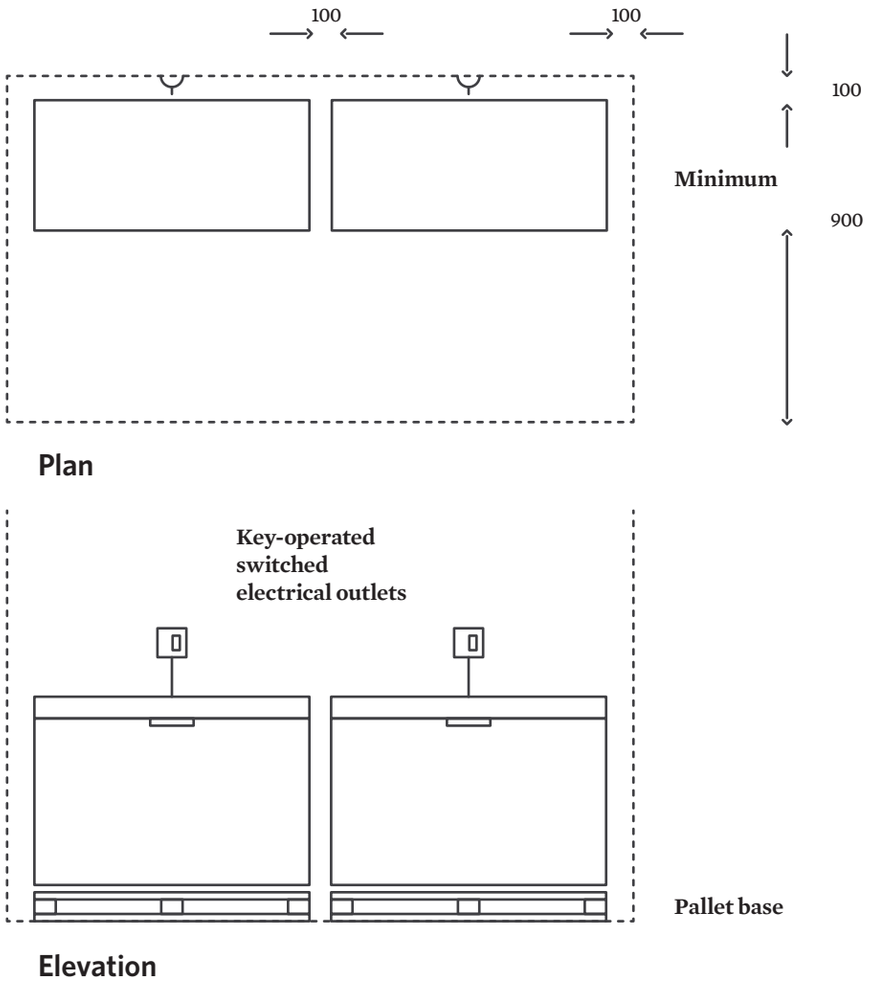
Typical cold room dimensions (internal height 2.2 metres)



Typical plan **Typical section**

Figure A2:

Refrigerator and Freezer Layout



Notes:

1) For estimating purposes allow 1.5m2 of floor area for every 100 litres of vaccine. The room volume should not be less than 4.5m3 per 100 litres of vaccine.

Figure A3:

Storekeeper's Office

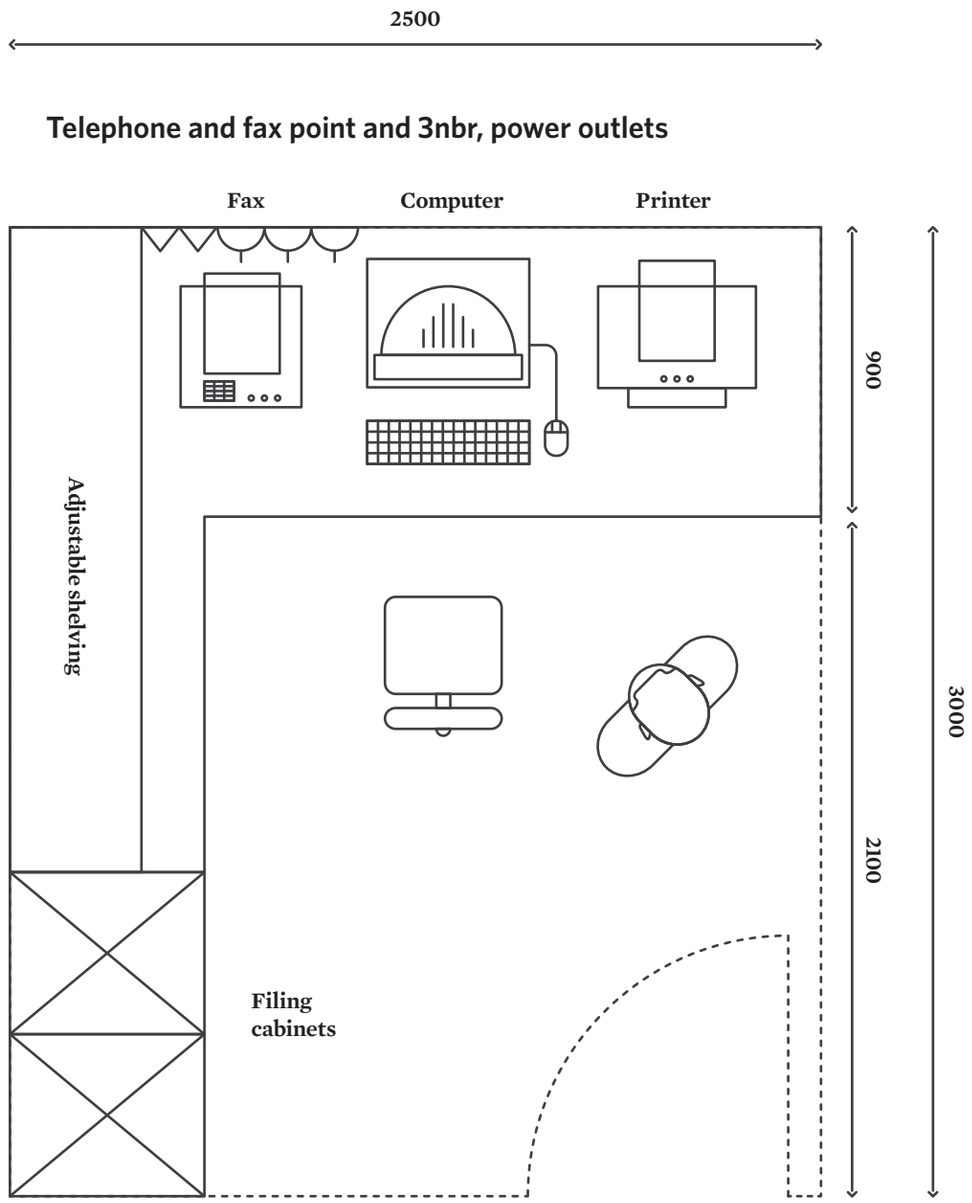
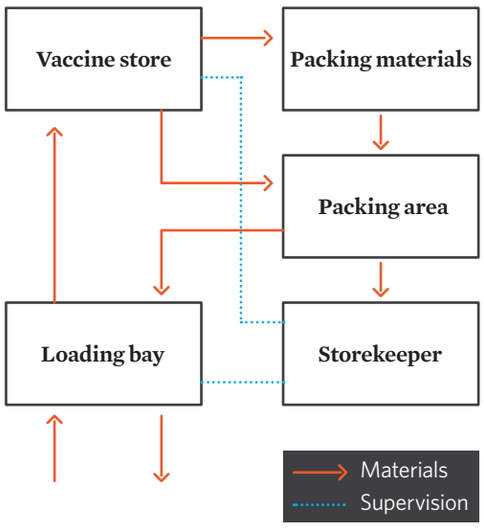


Figure A4:

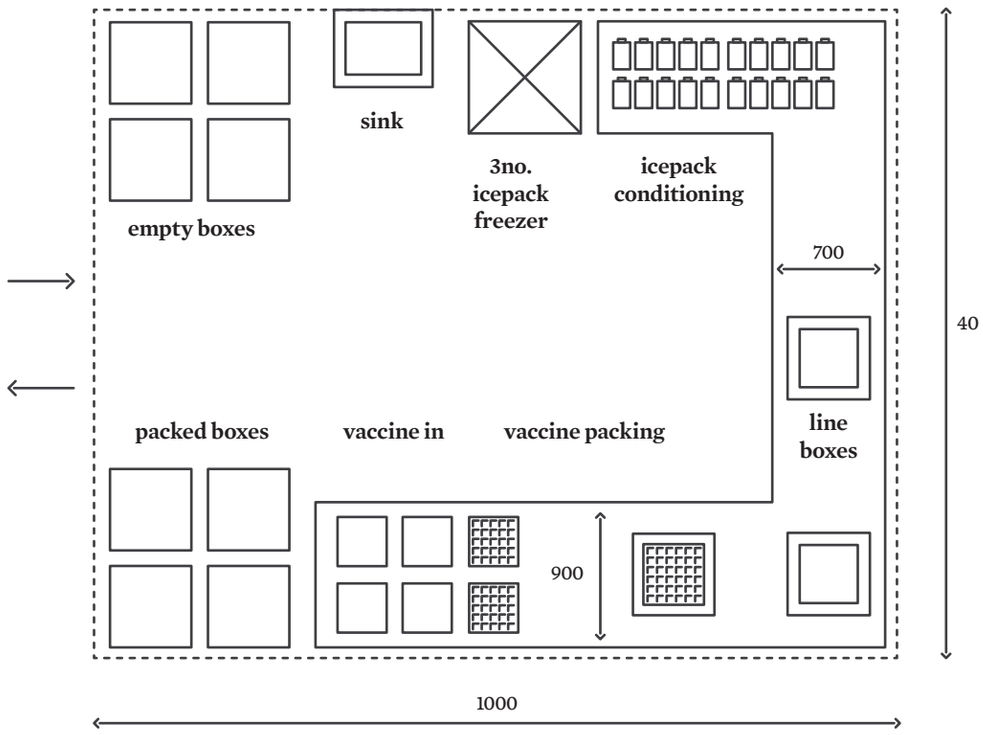
Vaccine Packing Area



Organisation diagramme

Notes:

1) Packing area should be air-conditioned in hot climates
2) Size of packing area depends number of incepacks and freezers required for maximum workload. See Worksheet
3) Provide adequate layout space for icepack conditioning. 20kg icepacks requires 1.0m2 work surface. 1.0m2 can about 60kgs per



Layout of packing area

- **Activity 1:** A written delivery order is received from the storekeeper.
- **Activity 2:** The correct quantities of vaccine and diluent are brought from the vaccine store and placed on the work surface.
- **Activity 3:** The order for each destination is assembled and checked and the delivery notes are completed.
- **Activity 4:** The correct number of icepacks are removed from the icepack freezer and laid out in a single layer on the work surface until they are 'conditioned'. (See packing procedures for vaccines and diluent).
- **Activity 5:** The insulated transport boxes are lined with conditioned icepacks.
- **Activity 6:** Vaccine is packed into the transport boxes and the boxes are secured/ sealed and stacked ready for loading on to the delivery vehicle.
- **Activity 7:** Transport boxes are loaded on to the vehicle.

If refrigerated transport is used then activities 4 and 5 will not be applicable.

Packing areas should be laid out to encourage a logical flow of work. Vaccines should be moved around as little as possible in order to minimize the risk of breakages. There should be a sink in the packing area for hand washing.

6. Storekeeper's office

Figure A3 shows the layout for the vaccine storekeeper's office. The office should be located as close as possible to the vaccine store, the packing area and the loading bay. This helps the storekeeper to supervise activities. There should be adequate space and connections for a telephone, a fax machine and a computer terminal.

7. Sizing and Planning Packing Material Stores

Transport boxes, cold boxes and other packing materials should be stored as close as possible to the vaccine packing area.

The volume of transport boxes received with each international vaccine shipment should be calculated. The room-by-room schedule allows for storage of 50 boxes, each 420 x 420 x 370. These boxes will be used for onward shipment to provincial stores. The packing materials store needs to be large enough to hold them.

8. Air-conditioning

The vaccine packing area may need to be air-conditioned. The office may also need to be air-conditioned. The temperature of the vaccine packing area should be kept between +15°C and +20°C. It must not exceed +25°C.

9. Vehicle loading bays

The detailed design of vehicle loading bays is governed by the size and type of vehicle used. The following points should be considered:

a) Access: The loading bay and its access route must be planned to allow easy access for the largest vehicle used

b) Security: Some vaccines might have a black market value. The loading bay area should therefore be visible from the storekeeper's office. Security is a particular problem if the vaccine store is located in a medical stores compound where other valuable commodities are also kept.

c) Weather protection: Loading bays should have a projecting canopy to protect the workers, the vehicle and the vaccines from sun, rain or snow during loading and unloading.

d) Loading dock: Delivery vans can be loaded from ground level. However it is more convenient to load and unload trucks from a loading dock at the same level as the floor of the vehicle. This allows vaccine to be wheeled into the vehicle on a trolley. Alternatively the truck may be fitted with a tail lift. Raised loading docks should be between 1.2 and 1.4 metres above the vehicle parking area. Ideally they should be built to suit the height of the delivery vehicle or fitted with a dock leveling device.

10. Choice of site

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

a) **Determine the size of the store and its access requirements:**
Using the information set out in the room by room schedule, calculate the floor area required for the vaccine storage and the size of delivery vehicles that will access the store premises.

b) **Review potential sites:** Consider the following:
Sites belonging to Authority
Sites which are for sale and could be bought by the Authority

c) **Compare site suitability:**
Consider the following issues before a site is finally selected:

Access:
- Is the site close to the relevant transport links, including roads and airport?
- Is the site well served by public transport? Public transport is needed by store staff. It may also be required by health workers coming to collect vaccine.
- Is the site conveniently located for permanent and supervisory staff?
- Is the route to the site accessible all year round?
- Is there adequate access and parking space for vehicles?

Services:
- Does the site have a reliable mains electricity supply?
- Is there an existing standby generator?
- Does the site have a reliable telephone service?

Security:
- Is the site secure?
- Could the store be properly monitored and supervised outside normal working hours?

Site development:
- Is the site well-drained and without any risk of flooding?
- Are ground conditions suitable for building economically?
- Can the site be developed at an acceptable cost?

Future conditions:
Will access to the site and the security of the electricity and communications systems be adversely affected by future development in the area?

11. Power Factors

11.1 Reliability

The reliability of the electricity supply is a key issue when choosing refrigeration equipment. Where power cuts exceed 8 hours in 24 hours, the use of ice-lined refrigerators and freezers is essential.

11.2 Standby generators

No refrigeration equipment currently available has a holdover time greater than 2.5 days. Vaccine will be destroyed if there is an extended mains power failure unless there is an alternative source of power. It is essential to assess the risk of such failure. Failures may arise for many reasons. Examples include overloading of the power supply network; mechanical breakdown; lack of fuel or seasonal storms.

Replacing large quantities of damaged vaccine is expensive and extremely disruptive. It may not be possible to replace vaccines quickly because there is limited availability of stocks with manufacturers/suppliers. Emergency replacement from a finite world stock also disrupts the supply of vaccines to other countries.

All sites storing large quantities of vaccine should have a standby power supply. Often this is achieved most economically by locating the vaccine store in a hospital compound or on some other site which already has a standby generator. When this is not possible it may be necessary to install a generator to serve the vaccine store alone.

11.2.1 Generator sizing and selection

WHO/UNICEF Product Information Sheets give advice on choosing and buying a generator and the EPI Equipment Performance Specifications provide detailed specifications.

11.2.2 Generator Control and Operation

Generators serving vaccine stores only should be fitted with automatic starting devices linked into the cold room or refrigerator/freezer alarm system. If the vaccine store is served by a compound generator, this will generally be started by an automatic mains failure device. In such cases alarm-triggered start-up is not required.

All generators should be run at least once per week and should be regularly serviced to ensure that they remain operational. The fuel tank should be kept full at all times.

11.2.3 Generator Sitting, Security and Fire Protection

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

11.2.4 Assuring Fuel Supplies

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

11.3 Voltage Stability

Voltage fluctuations greater than 4 15% will damage compressor motors. The problem can be overcome by fitting each piece of refrigeration equipment with a voltage stabilizer. Some of the refrigerators and freezers in the Product Information Sheets are supplied with integral voltage stabilizers.

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

- Actual voltage fluctuations (recorded by an engineer or electrician)
- Nominal voltage
- Single or three phase supply
- Frequency (50 Hz or 60 Hz)
- Nominal power of compressor in watts

The nominal power of the stabilizer should be about five times greater than the nominal power of the compressor to allow for the starting load. The tenderer will specify the voltage stabilizers required.

12. Building Standards

Vaccine stores should be housed in permanent buildings. These should be designed and constructed to a good standard to suit local climatic conditions. Temporary buildings should be avoided.

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

The following minimum standards are desirable in any vaccine storage building. All are essential in a national or regional store:

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

Walls and columns
- In good condition, free of cracks and other structural defects
- Free from rising or penetrating dampness
- Finished internally and externally to a good standard. Internal finishes should be dust-free

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

Floors
- Smooth,, leveled and completely free from rising dampness
- Finished with floor paint, tiles, terrazzo, vinyl sheet or other washable non-dusting surface

- Floors on which cold rooms are to be built must be leveled to a tolerance of 43mm over the area of the cold room
- Ideally cold rooms should be raised on a low plinth (25-50mm). This prevents water used for floor washing from running under the cold room floor panels. Alternatively the junction between the cold room and the floor may be sealed with waterproof mastic.

Fire protection

- The building should be easily accessible by the fire service. If the fire service requires fire hydrants these should be provided
- The building should not accommodate other functions which constitute a fire hazard, for example, a kitchen
- The building should be of non-combustible construction or should be lined with non-combustible sheet materials
- Rooms used for storing packing materials and other combustible items should be isolated from the vaccine store by fire-resistant construction and by fire-resistant self-closing doors
- The building should be fitted with fire and smoke alarms with an external sounder
- There should be at least one carbon dioxide or powder fire extinguisher close to the refrigeration equipment and this may be used to extinguish electrical fires
- In addition there should at least two carbon dioxide, powder or water extinguishers located within 30 metres of any part of the vaccine store. These may be used to extinguish other types of fire[2].

Electrical services

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

Heating and water supply systems

- All pipe work should be in good condition and free of leaks
- Heating systems should be fully operational and controllable

Drainage

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

Pests/Vermin

- Buildings should be designed and maintained so as to minimize colonization by insects, rodents, bats or other vermin.

Security

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

2. Source: These recommendations are based upon British Standard 5306, Part III: Code of Practice for Selection and Installation of Portable Fire Extinguishers. In general the number, size and type of extinguishers should conform to local fire authority requirements. In the absence of specific local requirements, BS 5306 recommendations may be followed. Fire extinguishers made to British Standards are given a size rating followed by a letter conforming to the class of fire (e.g. 20A). Vaccine stores require Class A extinguishers. The total Class A rating should be greater than 0.065 x the floor area of the store in square metres, but not less than 26A.

Room by Room Schedule

Number	Room Title	Remarks	Net area m2	Number of units	Total net area m2
1	Cold Room Area	size depends on Province, set in 2 banks with central aisle 2.5 m wide	?	1	?
2	Vaccine packing area	direct access to the cold room area	30	1	30
3	Store Keeper's office	direct access to the vaccine packing area	8	1	8
4	Loading bay	direct access to the cold room area and the packing area(does not include parking space for vehicles)	8	1	8
5	Store	Adjacent storekeeper's office	4	1	4
6	Toilets	1 male 1 female	3	2	6
7	Diluent store	adjacent packing area	20	1	20
8	Packing materials store	for 50 boxes	5	1	5
	Sub total				81
	Circulation space	20% of net area			17
				Gross Area	98

Appendix 2:

Job Description, National Cold Chain and Vaccine Manager

A2

Job details

Current job holder	
Job title	National Cold Chain and Vaccines Manager
Existing grade	Chief Pharmacist - Assistant director
Unit	
Location	Department of Health, Pretoria

Job purpose

- To ensure optimal management of all vaccines
- To facilitate the development of a risk management policy for vaccines
- To facilitate the standardisation of injection safety through the safe destruction of clinic waste
- To monitor and evaluate the impact of training in the vaccine management system
- To facilitate the equitable distribution of all vaccines in the public sector in South Africa

Dimensions
Organisation chart

Knowledge, Skills, Experience Required

- Registration as a pharmacist with the South African Pharmacy Council
- Computer literacy: (Knowledge of word processing, spreadsheets and presentations)
- Good knowledge of logistical processes, and temperature sensitive medicines
- Experience in the training of health care workers, standard operating procedures for the management of vaccines and other heat sensitive pharmaceuticals
- Knowledge of relevant legislation
- Basic knowledge of the National Qualifications Framework

Key Performance Areas

Establish a process for the flow of information regarding vaccine usage, wastage, quantities and distribution so that the management of vaccines becomes more efficient and cost effective at national level

a) Optimise the policies and management of vaccines and injection safety
b) Facilitate the establishment of relevant training programmes for both the public and private sectors.
c) Evaluate the management of vaccines and the impact of training programmes through provincial reviews of cold chain management and the management of injection safety
d) Liaise with the Expanded Programme on Immunisation on all pharmaceutical matters to improve communication on vaccine and drug related problems, especially new vaccine additions and Adverse Events Following Immunisation (AEFI)

Duties:

- review, update, reprint and facilitate the implementation of the national guidelines on cold chain operations
- update training material for district level training in the technical aspects of cold chain management
- co-ordinate the provincial investigations into adverse events after immunisation, with respect to role of the vaccine
- co-ordinate communication with all provinces. This includes a weekly telephonic contact with the vaccines manager, the follow-up of problems and the feedback to the EPI staff meetings on matters arising out of these discussions
- facilitate training workshops at relevant levels to improve the standard of the management of vaccines countrywide.
- to facilitate provincial vaccine distribution to ensure cold chain management at all stages through to the patient.
- to update the Multi-dose Vial Policy for the country, adapted from the latest WHO policy;
- to participate in the EPI mini reviews in the provinces as a national expert on cold chain and lead the cold chain group in the report writing sessions;
- to attend relevant meetings,
- to attend Board of Governors meetings of the Collaborative Centre for Cold Chain Management;
- to compile the agendas and minutes of the cold chain component of the EPI& vaccine co-ordinators meetings;
- to participate in the EPI& Vaccine co-ordinators Task Group meetings;
- to manage guidelines on the discarding of possibly damaged vaccines when exposed to heat or freezing
- to liaise with vaccine manufacturers/suppliers in collaboration with other members of the Directorate;
- to respond to relevant questions or queries
- to respond to Ministerial queries;
- to assign and manage duties related to the key performance areas of vaccine distribution as per the business plan

Communications and Working Relationships:

Sub-directorate and other Directorate staff
Other directorates within the Department of Health and their staff
Provincial vaccine co-ordinators and EPI co-ordinators
Provincial Depot managers
Pharmaceutical and related items suppliers
Cold chain equipment suppliers
WHO personnel including SADAP, the cold chain, logistics and EPI officials
Representatives of International organisations e.g. Vaccine manufacturers/suppliers
CSIR
Collaborative Centre for Cold Chain Management
SADC
Public and the media

EPI Cold Chain Manager	Deputy Director
Date:	Date:

Appendix 3:

Daily temperature record chart

A3

Daily temperature records for refrigerators

Facility: ..... Month/Year: ..... District: .....

Record temperature at 08:00 and 16:00 daily

Deg. C		1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		16		17		18		19		20		21		22		23		24		25		26		27		28		29		30		31	
		M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A	M	A
UNSAFE	22																																																																			
	20																																																																				
	18																																																																				
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SAFE	8																																																																			
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UNSAFE	0																																																																			
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	-4																																																																				
	-6																																																																				
	-8																																																																				
	-10																																																																				
Defrost																																																																				

Action to take when the temperature moves into the UNSAFE range

1. Check the electricity supply connection. Check the gas supply - is ther a spare gas cylinder? Is ther sufficient kerosene?
2. Does the door close properly? Has anyone left the door open for a while? Is the fridge opened often? Is the fridge overloaded?
3. How thick is the ice build-up in the freezing compartment? DEFROST IF THE ICE IS MORE THAN 0.5CM THICK - clean fridge regularly
4. Implement your contingency plan if the fridge is malfunctioning

Appendix 4:

Vaccine storage capacity calculator showing the maximum packed volume for each type of vaccine and presentation

A4

Vaccine product	Vaccine formulation	Mode of adminis-tration	Manufacturer trade mark	Vaccine presentation	Vaccine presentation packaging with		No. of doses per vial (doses/vial)	Packed volume per dose, cm3		Vaccine Manufacturer or Source of data
					diluents	*syringe*		*vaccines*	*diluents/drop.*	
BCG vaccine	freeze-dried	ID		1 vial/ampoule + diluents	w/o diluents		10	1.2	0.7	WHO Intern. Shipping guidelines
BCG vaccine	freeze-dried	ID		1 vial/ampoule + diluents	w/o diluents		20	1.2	0.7	WHO Intern. Shipping guidelines
BCG vaccine	freeze-dried	ID	BCG Vaccine SSI	boxes of 50 vials of 10-doses of vaccine + diluents	w/o diluents		10	2.2	1.1	Statens Serum Institute
Diphtheria-Tetanus paediatrics	liquid	IM		1 vial			10	3.0		WHO Intern. Shipping guidelines
DaTP-IPV-Hib-HBV	liquid	IM	HEXAXIM	pack of 1 prefilled syringe		Prefilled syringe	PFS	107.4		Sanofi Pasteur
Hepatitis B	liquid	IM		1 vial			1	18.0		WHO Intern. Shipping guidelines
Hepatitis B	liquid	IM		1 vial			2	13.0		WHO Intern. Shipping guidelines
Hepatitis B	liquid	IM		1 vial			6	4.5		WHO Intern. Shipping guidelines
Hepatitis B	liquid	IM		1 vial			10	4.0		WHO Intern. Shipping guidelines
Hepatitis B	liquid	IM		1 vial			20	3.0		WHO Intern. Shipping guidelines
Hepatitis B	liquid	IM		1 vial			10	2.6		LG, Korea
Hepatitis B	liquid	IM	Hepavax	boxes of 50 vials of single-doses of vaccine			1	13.3		Berna Biotech Korea Corp.
Hepatitis B	liquid	IM	Hepavax	boxes of 50 vials of 2-doses of vaccine			2	6.7		Berna Biotech Korea Corp.
Hepatitis B	liquid	IM	Hepavax	boxes of 20 vials of 10-doses of vaccine			10	3.3		Berna Biotech Korea Corp.

Vaccine product	Vaccine formulation	Mode of adminis-tration	Manufacturer trade mark	Vaccine presentation	Vaccine presentation packaging with		No. of doses per vial (doses/vial)	Packed volume per dose, cm3		Vaccine Manufacturer or Source of data
					diluents	*syringe*		*vaccines*	*diluents/drop.*	
Hepatitis B	liquid	IM	Hepatitis B Vaccine Recombinant	boxes of 100 vials of single-doses of vaccine			1	12.0		Bio Farma
Hepatitis B	liquid	IM	Heberbiovac HB	boxes of 10 vials of single-doses of vaccine			1	2.8		Center for Genetic Engineering and Biotechnology
Hepatitis B	liquid	IM	Euvax B	boxes of 10 vials of 10-doses of vaccine			1	14.4		LG Life Sciences Ltd.
Hepatitis B	liquid	IM	Euvax B	boxes of 50 vials of 10-doses of vaccine			10	3.2		LG Life Sciences Ltd.
Hepatitis B	liquid	IM	EnivacHB	boxes of 50 vials of single-dose of vaccine			1	19.2		Panacea Biotec
Hepatitis B	liquid	IM	Revac-B+	boxes of 30 vials of 6-dose of vaccine			6	5.3		Bharat Biotech International Ltd.
Hepatitis B	liquid	IM	Revac-B+	boxes of 30 vials of 10-dose of vaccine			10	3.2		Bharat Biotech International Ltd.
Hepatitis B	liquid	IM	Revac-B+	boxes of 30 vials of 20-dose of vaccine			20	2.0		Bharat Biotech International Ltd.
Hib liquid	liquid	IM		1 vial			1	15.0		WHO Intern. Shipping guidelines
Hib liquid	liquid	IM		1 vial			10	2.5		WHO Intern. Shipping guidelines
Hib freeze dried vaccine	freeze-dried	IM		1 vial + diluents	w/o diluents		2	6.0	6.0	WHO Intern. Shipping guidelines
Hib freeze dried vaccine	freeze-dried	IM		1 vial + diluents	w/o diluents		10	2.5	3.0	WHO Intern. Shipping guidelines
Hib freeze dried vaccine	freeze-dried	IM		1 vial + diluents	w/o diluents		1	9.7	9.7	GlaxoSmithKline
Japanese Encephalitis	freeze-dried	SC	CD.JEVAX (SA14-14-2-Live)	pack of 10 single-dose vials	w/o diluents		1	11.5	11.5	Chengdu Vaccine (China)
Japanese Encephalitis	freeze-dried	SC	CD.JEVAX (SA14-14-2-Live)	pack of 100 five-dose vials	w/o diluents		5	2.5	2.9	Chengdu Vaccine (China)
Japanese Encephalitis	freeze-dried	SC	CD.JEVAX (SA14-14-2-Live)	pack of 100 single-dose vials	w/o diluents		1	12.6	11.5	Chengdu Vaccine (China)
Measles vaccine	freeze-dried	SC		1 vial + diluents	w/o diluents		10	3.5	4.0	WHO Intern. Shipping guidelines

Vaccine product	Vaccine formulation	Mode of adminis-tration	Manufacturer trade mark	Vaccine presentation	Vaccine presentation packaging with		No. of doses per vial (doses/vial)	Packed volume per dose, cm3		Vaccine Manufacturer or Source of data
					diluents	*syringe*		*vaccines*	*diluents/drop.*	
Measles vaccine	freeze-dried	SC		1 vial + diluents	w/o diluents		1	9.3		Aventis Pasteur
Measles vaccine	freeze-dried	SC	Measles Vaccine ,Live, attenuated	boxes of 50 vials + diluents	with diluents		1	26.1		Serum Institute of India Ltd, India
Measles vaccine	freeze-dried	SC	Measles Vaccine ,Live, attenuated	boxes of 50 vials + diluents	w/o diluents		10	2.6	4.0	Serum Institute of India Ltd, India
Measles vaccine	freeze-dried	SC	ROUVAX	boxes of 10 vials of 10-doses vaccine+10 vials of 5ml diluent.	w/o diluents		10	2.5	4.0	Sanofi Pasteur
Meningococcal A conjugate	freeze-dried	SC		1 vial + diluents	with diluents		10	3.8		Serum Institute of India
Measles-Mumps-Rubella vaccine	freeze-dried	SC		1 vial + diluents	w/o diluents		1	16.0	20.0	WHO Intern. Shipping guidelines
Measles-Rubella vaccine	freeze-dried	SC		1 vial + diluents	w/o diluents		10	2.5	4.0	WHO Intern. Shipping guidelines
Meningococcal A/C	freeze-dried	SC		1 vial + diluents	w/o diluents		20	2.5	2.5	WHO Intern. Shipping guidelines
Meningococcal A/C	freeze-dried	SC		1 vial + diluents	w/o diluents		50	1.5	1.5	WHO Intern. Shipping guidelines
Meningococcal A/C7W/Y	freeze-dried	SC		1 vial + diluents	with diluents	with syringe	PFS	272.2		GlaxoSmithKline
Oral polio	liquid	Oral		1 vial			10	2.0		WHO Intern. Shipping guidelines
Oral polio	liquid	Oral		1 vial			20	1.0		WHO Intern. Shipping guidelines
Pneumococcal Conjugate Vaccine 13-valent	liquid	IM	Prevnar®	packs of 10 single doses+ syringe		Prefilled syringe	PFS	55.9		Wyeth
Pneumococcal Conjugate Vaccine xxx-valent	liquid	IM		Uniject type of presentation		Compact AD-PFD	Uniject	11.0		Assumption (WHO TPP)
Rotavirus vaccine	liquid	Oral	Rotarix®	box of 50 single-dose polyethylene tubes with 5 rows of 10 tubes			1	17.1 v		GlaxoSmithKline

Vaccine product	Vaccine formulation	Mode of adminis-tration	Manufacturer trade mark	Vaccine presentation	Vaccine presentation packaging with		No. of doses per vial (doses/vial)	Packed volume per dose, cm3		Vaccine Manufacturer or Source of data
					diluents	*syringe*		*vaccines*	*diluents/drop.*	
Rotavirus vaccine	liquid	Oral	Rotarix®	box of 10 single-dose polyethylene tubes with 2 rows of 5 tubes			1*	43.3		GlaxoSmithKline
Rotavirus vaccine	liquid	Oral	Rotarix®	box of one single-dose polyethylene tube			1*	115.3		GlaxoSmithKline
Rotavirus vaccine	liquid	Oral	Rotarix®	box of one blister of one oral applicator			1*	134.1		GlaxoSmithKline
Rotavirus vaccine	liquid	Oral	Rotarix®	box of 2 blisters with 5 oral applicators			1*	85.3		GlaxoSmithKline
Rotavirus vaccine	freeze-dried	Oral	Rotarix®	box of 1 vial of vaccine + diluents + transfer adapter	with diluents		1*	256.0		GlaxoSmithKline (WHO P/Q file)
Rotavirus vaccine	freeze-dried	Oral	Rotarix®	box with 2 blisters of 5 syringes of diluents, 1 plastic bag with ten transfer adapter + 1 box with ten vials of vaccine	with diluents		1*	156.0		GlaxoSmithKline (WHO P/Q file)
Rotavirus vaccine	freeze-dried	Oral	Rotarix®	one pack of 25 single-dose vaccine + diluents in cold chain	with diluents		1	110.6		GlaxoSmithKline
Rotavirus vaccine	freeze-dried	Oral	Rotarix®	one pack of 25 single-dose vaccine w/o diluents	w/o diluents		1*	10.5	88.5	GlaxoSmithKline
Tetanus-diphtheria for adults	liquid	IM		1 vial			10	3.0		WHO Intern. Shipping guidelines
Tetanus-diphtheria for adults	liquid	IM		1 vial			20	2.5		WHO Intern. Shipping guidelines
Tetanus toxoid	liquid	IM		1 vial			10	3.0		WHO Intern. Shipping guidelines
Tetanus toxoid	liquid	IM		1 vial			20	2.5		WHO Intern. Shipping guidelines
Tetanus toxoid	liquid	IM				Uniject	Uniject	25.0		WHO Intern. Shipping guidelines
Yellow Fever	freeze-dried	SC	Stabilized Yellow Fever Vaccine	10 Vials 5 doses + 10 vials 5 ml (diluent)			5	2.8	7.0	Institut Pasteur Dakar
Yellow Fever	freeze-dried	SC	Stabilized Yellow Fever Vaccine	10 Vials 20 doses + 10 vials 5 ml (diluent)			20	0.7	3.0	Institut Pasteur Dakar
Yellow Fever	freeze-dried	SC	Stabilized Yellow Fever Vaccine	20 Vials 10 doses + 20 vials 5 ml (diluent)			10	1.4	6.0	Institut Pasteur Dakar

Appendix 5:
Monthly summary reporting format

A5

Reporting Facility ..... ***Reporting Period*** .....

Commodity name	Opening balance (doses)	Received (doses)	Issued (doses)	Losses/Adjustments (doses)	End balance (doses)	AMC	Stock level (months)
A	*B*	*C*	*D*	*E*	*F*	*G*	*H*
OPV							
BCG							
RV							
DTaP-IPV-Hib-HBV							
Hep B							
PCV 13							
MEASLES							
Td							
TT							

Explanation for loses or adjustment:

Reported by..... ***Date*** .....

Title .....

Key:

Reporting facility:	*Name of the facility sending the report.*
Reporting period:	*Indicated as dd/mm/yyyy to dd/mm/yyyy that reporting period corresponds*
Commodity name (A):	*It is recommended to preprint commodity names. By doing this, same items will appear in the same line in all reports for easier comparison and evaluation.*
Opening balance (B):	*Number of commodities on stock at the beginning of reporting period. Beginning stock should be equal to end balance (F) of the previous report.*
Received (C):	*Number of commodities received during reporting period.*
Issued (D):	*Number of commodities issued during reporting period.*
Loss/Adjustments (E):	*Losses are commodities removed from the system for any reason other than consumption (e.g., theft, loss, expiry). Adjustments are the difference between calculated ending balance and physical count. If result of physical inventory is less than the calculation, then it should be recorded as a minus value.*
End balance (F):	*Balance is equal to B+C-D4E*
AMC (G):	*Most recent Average Monthly Consumption*
Stock level (H):	*Ending balance (F) divided by AMC (G). Shows the number of months that stocks will last.*
Explanation for losses and adjustments	*Losses and adjustments should be explained*

Cold chain incident check list

Follow steps 1-5 and complete the table below:

1. Isolate the vaccines in a **+2°C to +8°C** environment and clearly label 'do not use
2. Record the type and quantity of vaccines involved in the cold chain breach
3. Contact cold chain manager as soon as possible
4. Do not discard any vaccines until advice from your cold chain manager

Take active steps to correct and prevent the problem recurring Date of the breach	
What was the temperature reading when the breach was noticed?	
How long was the temperature outside 2 to 8°C ?	
When was the accuracy of the thermometer last checked?	
Are the vaccines frozen?	
Are the vaccines in their original package?	
What do you think was the cause of the cold chain breach?	
Has the cause of the breach been rectified?	
How long do you think these problems have been occurring?	
Are you using kitchen fridge or vaccine fridge?	
Is the cooler box temperature monitored?	
Are the ice packs still cold?	
Has anyone been vaccinated with these potentially affected vaccines?	

Cold chain managers contact list:

Eastern Cape:

Western Cape:

Northern Cape:

North West:

KwaZulu Natal:

Limpopo:

Mpumalanga:

Gauteng:

Free State:

National:

Selected resource materials for further reading

1. Department of Health, Expanded Program on Immunisatons: Cold chain and immunisation operation manual; June 2003

2. World Health Organization, Department of Immunisation, Vaccines and Biologicals: Vaccine-management assessment, 2005

3. World Health Organization, Department of Immunisation, Vaccines and Biologicals: Guidelines on the international packaging and shipping of vaccines, 2005

4. World Health Organization, Department of Immunisation, Vaccines and Biologicals: Vaccine stock management, September 2006

5. World Health Organization, Department of Immunisation, Vaccines and Biologicals: Temperature sensitivity of vaccines, August 2006

6. World Health Organization, Department of Immunisation, Vaccines and Biologicals: WHO Policy Statement: The use of opened multi-dose vials of vaccine in subsequent immunisation sessions, March 2000

7. World Health Organization, Department of Immunisation, Vaccines and Biologicals: WHO-UNICEF Effective Vaccine Store Management (EVSM) initiative, January 2005

8. World Health Organization, Department of Immunisation, Vaccines and Biologicals: How to look after a cold room or freezer room: a self-assessment tool, 2002

9. World Health Organization, Department of Immunisation, Vaccines and Biologicals: Making use of Vaccine Vial Monitors: Flexible vaccine management for polio, 2000

10. World Health Organization, Department of Immunisation, Vaccines and Biologicals: Getting started with vaccine vial monitors; December, 2002

11. World Health Organization, Department of Immunisation, Vaccines and Biologicals: User's handbook for vaccine cold rooms and freezer rooms, December 2002

12. World Health Organization, Department of Immunisation, Vaccines and Biological: Guideline for establishing or improving primary and intermediate vaccine store, December 2002

13. The Public Health Agency of Canada: National Vaccine Storage and Handling Guidelines for Immunisation Providers, 2007

14. World Health Organization, Department of Immunisation, Vaccines and Biological: Temperature monitors for vaccines and the cold chain, July 1999

15. Common wealth Australia: National vaccine storage guidelines, 2005

16. Department of Health and Human Services, Centers for Disease Control and Prevention: Epidemiology and Prevention of Vaccine-Preventable Diseases, May 2011

17. World Health Organization: Mid-level management training -Module 1: Cold chain, vaccines and safe-injection equipment management, 2008

18. World Health Organization: Logistics planning tool, 2010

19. World Health Organization: Logistics forecasting tool, 2010

20. World Health Organization: Vaccine volume calculator

21. Department of Health and Human Services, Centers for Disease Control and Prevention: vaccine storage and handling guide, 2011

22. World Health Organization &UNICEF: Ensuring the quality of vaccines at country level; Guidelines for health staff, October, 2002

23. WHO-UNICEF-GAVI-PATH: Effective Vaccine Management Initiative; September 2010