

**COLD CHAIN
AND
IMMUNISATION
OPERATIONS MANUAL**

**Guidelines for handling heat sensitive vaccines
and pharmaceuticals**

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Foreword to the Cold Chain and Immunisation Operations Manual.

Immunisation remains one of the most cost effective means of reducing disease in a nation. Poliomyelitis caused by the wild poliovirus has not been seen for fifteen years, and today there are no deaths from measles. The diseases that are prevented by the vaccines given in our Expanded Programme on Immunisation (EPI) are both debilitating and fatal, and would be a huge burden both financially and socially on South Africa

If we are to eradicate the poliomyelitis virus and eliminate measles from South Africa, we need to reach as many of our children in our immunisation programme as we can. It goes without saying that if the vaccine we use in both the routine EPI as well as in vaccination campaigns is not potent, our efforts will be wasted, and we will see the dread diseases once again.

The first South African Cold chain manual was the first comprehensive guideline for the management of vaccines and related items globally. The information was distributed to other interested countries, and there are now a number of similar manuals in many different languages. The World Health Organisation has a good tool for assessing vaccine handling and management, and we in South Africa are adopting it with slight changes to suit our own conditions of supply and storage.

This manual is the second edition and is a guideline for managing vaccines and their associated products at all levels of health care service. Each person handling or supervising vaccines, whether doctor, pharmacist, nurse or any other health provider should own a manual and use it as a reference to the handling and management of vaccines and related items.

Although the manual focuses mainly on the public sector because that is where the majority of childhood vaccinations are given, its message is clear for private health practitioners. Some of the sections are specific to the public sector, but most are a valuable guideline for both sectors.

During the next few years we will be looking to change to refrigerators with CFC friendly gases, and where possible, vaccine specific fridges should be purchased. These fridges are designed to keep a more constant temperature, especially when there are power failures, and they are more efficient, and thus cost less to run. Audits on refrigeration equipment are being done in the provinces and the costs of change will be calculated. Many of our fridges are very old, and will have to be written-off in favour of new equipment, or, if possible modified to use the new gases. There is a display of the vaccine fridges at the offices of the Pharmaceutical Society of South Africa in Pharmacy House in Pretoria, and prices for these can be requested from them at 012 301 0820.

No policy guideline is cast in stone, so there are a number of changes in this

manual toward better and more efficient management of vaccines. We were always concerned about the heat damage that can be done to vaccines, but we have discovered that there is a real danger of destroying vaccines through inadvertent freezing.

When we wrote the first Cold Chain manual, the principles of injection safety and safe disposal of sharps was almost unheard of. Thankfully today, most health care providers are now conscious of injection safety, and there are few, if any facilities not using approved disposal containers. Sadly, the destruction of these sharps in some areas still leaves much to be desired, with incinerators not operating properly, or shallow pits being dug in an attempt to burn the sharps and other clinical waste.

Use this manual to its best advantage, be passionate about the cold chain, take good care of the vaccines and they, in turn, will take good care of our children.

Dr A Ntsaluba
Director-General: Health

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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, DT, TT and Hep B. Vaccines containing an adjuvant are sensitive to freezing and may 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. 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

The health level managed by the district manager.

Flocculation/ Granulation

Granular particles (flocs) 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 Used in this Manual

| | |
|--------|--|
| BCG | Bacillus Calmette-Guérin vaccine |
| CCM | Cold Chain Monitor card |
| DoH | Department of Health |
| DPT | Diphtheria Pertussis Tetanus vaccine |
| DT | Diphtheria Tetanus vaccine |
| EPI | Expanded Programme on Immunisation |
| FEFO | First Expiry, First Out |
| FW | Freeze Watch card |
| Hep B | Hepatitis B vaccine |
| Hib | Haemophilus influenzae type b vaccine |
| NBC | New-born children |
| OPV | Oral Polio vaccine |
| PVC | Polyvinyl chloride (plastic) |
| RSA | Republic of South Africa |
| RH | Rhesus factor |
| SIA | Supplementary Immunisation Activity |
| TT | Tetanus Toxoid vaccine |
| Td | Tetanus vaccine with $\frac{1}{2}$ strength diphtheria vaccine |
| UNICEF | United Nations Children's Fund (Originally United Nations International Children's Emergency Fund) |
| VVM | Vaccine Vial Monitor |
| WHO | World Health Organisation |
| YF | Yellow fever vaccine |

1. Introduction

Immunisation is the most precious gift that a health care worker can give a child. Immunisation remains the most cost effective preventative health intervention 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 epidemiological plan, a supportive public which wishes to be immunised and operations management which can ensure that the plans and procedures are implemented effectively.

Why do we need an operations manual?

The 1994 review of the National Immunisation Programme 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 to a greater or lesser degree 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 almost impossible.

Why do we need a new operations manual?

Policies and procedures never remain static, but are dynamic processes which need updating at regular intervals. This edition of the Cold Chain Manual strives to include all of the updated policies and cater for the integration of vaccine management with drug supply management

This updated manual is the product of wide consultation, and is based on the needs of the provinces.

What is new or has changed in this edition of the Cold Chain and Immunisation Operations Manual

The original manual was written with the assistance of a consultant before the integration of EPI into Primary Health Care services.

There have been a number of small changes made to this edition of the manual to make it more relevant to the services offered, and in addition, some major changes have been made, or procedures added to the document.

Relevant changes:

Storage temperatures – Evidence shows that Hepatitis B vaccine is extremely freeze-sensitive and 0°C is too close to freezing for comfort. Even in transport, frozen ice packs are a danger to this vaccine.

Ice pack conditioning – It now takes far longer to condition an ice pack because the ice must ‘rattle’ in its pack to ensure that it will not freeze vaccine. In addition, the use of ‘cold packs’ instead of ice packs is demonstrated.

Shake test – It is often difficult to observe the floccules or granular particles in frozen vaccine. The new procedure allows for a comparison in sedimentation rates of a controlled frozen vaccine against suspected frozen vaccine.

Multi-dose Vial Policy (MDVP), formally Opened Vial Policy – this has changed from the original policy and should decrease wastage rates of vaccines that have a preservative as one of the components.

Vaccine Vial Monitor (VVM) – additional information on VVMs has been included to facilitate any new VVMs being introduced onto vaccines in the schedule.

Stock Cards – a new stock card, based on the stock card in use in the Eastern Cape, but with modifications to include batch numbers and expiry dates has been designed.

Estimates for vaccine supplies – the quantification of estimates has been aligned to those taught in the Drug Supply Management training courses.

Yellow fever vaccine has been included for vaccine management training in the private sector

Who is this manual written for?

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

- the National Managers, both EPI and vaccine
- the Provincial vaccine and EPI co-ordinators
- the 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
- minimum standards for 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.

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 standard operating procedures..

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. When this occurs in this manual the three levels are shown together in three columns. Those parts of the manual which are very

important are highlighted in the margin by the following symbol:



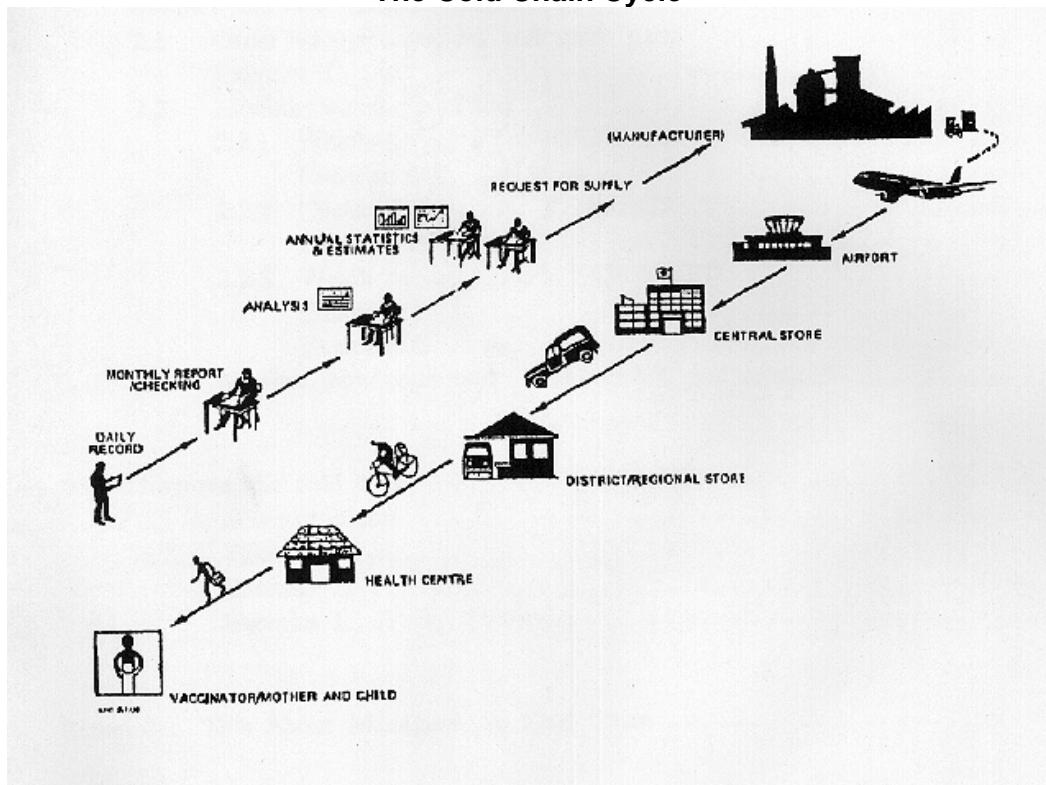
An extensive table of contents enables quick access to any aspect covered in this manual and it is requested that this guideline is kept to hand for easy reference in all situation

2. Operations Management

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 monitored by a pharmacist. Operations management includes the cold chain and the Cold Chain Cycle is illustrated in Figure 1

Figure 1
The Cold Chain Cycle



Typical post descriptions for cold chain and vaccine logistics managers and responsible people are shown for each level so that staff may understand their responsibilities and also see how those responsibilities compare with their counterparts at other levels. See Appendix 2 for National Cold Chain Manager's job description.

Job Descriptions

| Provincial Level | Sub Provincial/District Level | Clinic Level |
|--|---|--|
| <p>Provincial Cold Chain Operations Manager</p> <p>a) Provide management support to the EPI manager including assessment of the logistical implications resulting from programmatic decisions</p> <p>b) Ensure that relevant updated cold chain information is available to all staff involved in the cold chain.</p> <p>c) Ensure adequate formal and in-service training of all staff involved in vaccine management.</p> <p>d) Prepare budget estimates (financial and quantities) of vaccines and related medical items necessary for immunisation (syringes, needles, etc.).</p> <p>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.</p> <p>f) In conjunction with the sub-provincial/district vaccine managers, co-ordinate, monitor and approve orders for vaccines, and medical related items.</p> | <p>Sub-Provincial/district person responsible for Cold Chain & Vaccine Management</p> <p>a) Provide management support at sub provincial level.</p> <p>b) Ensure that relevant updated cold chain information is available to all staff involved in the cold chain.</p> <p>c) Ensure adequate formal and in-service training of all staff involved in vaccine management.</p> <p>d) Provide the Provincial Vaccine Manager with required budgetary data.</p> <p>e) Provide the Provincial Vaccine Manager with required wastage data.</p> <p>f) In conjunction with the Provincial vaccine managers, co-ordinate, monitor and approve orders for vaccines, and medical related items</p> | <p>Clinic person responsible for Cold Chain</p> <p>a) Ensure proper management of logistical aspects of EPI in the clinic</p> <p>b) Ensure that relevant updated cold chain information is available to all staff involved in the cold chain.</p> <p>c) Ensure that staff implement EPI and vaccine management training given.</p> <p>d) Provide district person responsible with required budgetary data.</p> <p>e) Provide district person responsible with required wastage data.</p> <p>f) Provide district person responsible with required vaccine and medical related item stock data.</p> |

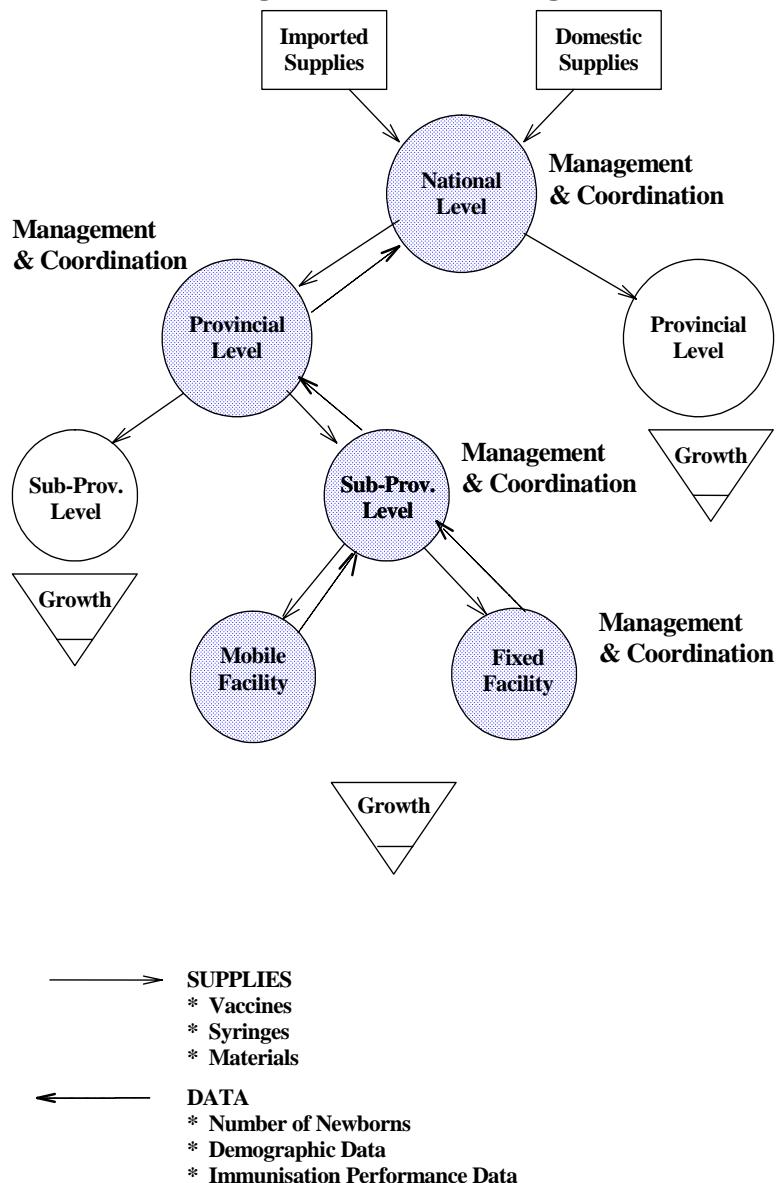
| Provincial Level | Sub Provincial/District Level | Clinic Level |
|--|---|---|
| <p>g) In conjunction with the provincial EPI manager and the main provincial medical stores, co-ordinate and plan the logistics for the cost-effective distribution of vaccine</p> <p>h) Maintain and ensure a constant cost effective supply/storage of heat sensitive products and medical related items for immunisation.</p> <p>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.</p> <p>j) Ensure the efficient usage of vaccines by limiting wastage and monitoring activity.</p> <p>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</p> <p>l) Assess staff requirements at different levels for the sub-provincial vaccine managers for EPI and monitor training needs.</p> | <p>g) Provide the Provincial Vaccine Manager with required distribution data</p> <p>h) Maintain and ensure a constant cost effective supply/storage of heat sensitive products and medical related items for immunisation.</p> <p>I) Monitor the quantity used and financial expenditure of vaccines and medical related items for immunisation and report monthly to the provincial/ district vaccine manager</p> <p>j) Ensure the efficient usage of vaccines by limiting wastage and monitoring activity.</p> <p>k) Ensure that data requested for a needs-analysis for adequate storage equipment is provided when requested.</p> <p>l) Provide data for assessing staff requirements at different levels for the district level staff.</p> | <p>g) Provide district person responsible with required data on receipt of vaccine and medical related items</p> <p>h) Maintain and ensure a constant cost effective supply/storage of heat sensitive products and medical related items for immunisation.</p> <p>I) Monitor the quantity of vaccines and medical related items used for immunisation and report monthly to the district person responsible.</p> <p>j) Ensure the efficient usage of vaccines by limiting wastage and monitoring activity.</p> <p>k) Ensure that data requested for a needs-analysis for adequate storage equipment is provided when requested.</p> <p>l) Provide data for assessing staff requirements at different levels for the clinic level staff.</p> |

| Provincial Level | Sub Provincial/District Level | Clinic Level |
|--|--|---|
| m) Liaise with the provincial EPI manager on disease outbreaks, and have contingency plans ready for these events. | m) Provide the Provincial Vaccine Manager with required data and implement contingency plans | m) 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. | n) In the event of a cold chain failure, make a decision on action to be taken , and/or liaise with the Provincial vaccine manager. | n) 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. | o) 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 | o) 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. | p) Conduct regular stock and documentation checks (audit) of all vaccines and medical related items. | p) 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. | q) Conduct annual audits of vaccines, medical related items and equipment. | q) Conduct annual audits of vaccines, medical related items and equipment. |

2.2 Organisation of EPI logistics

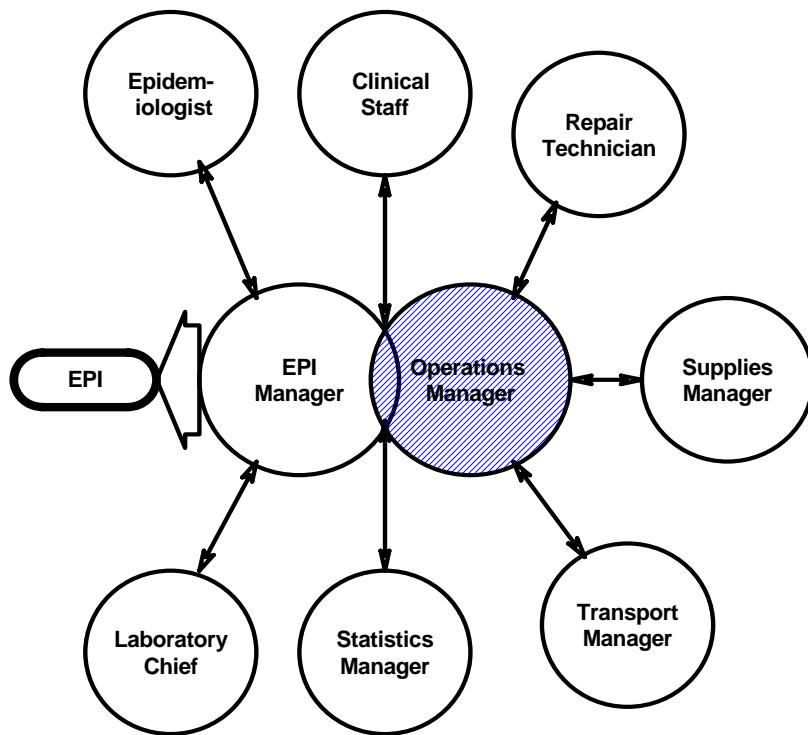
For the EPI programme to be effective it must have efficient logistics. The logistics will only be efficient if there is a team of staff, designated at each level, to be responsible for ensuring that operations are fully integrated with the EPI Programme. The structure and interdependence of such a model is illustrated in Figure 2.

Figure 2
The Organisation of EPI Logistics



The teamwork required ensuring the management and co-ordination illustrated in Figure 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 others 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 as shown, EPI management will not be effective.

Figure 3
Teamwork builds EPI Operations



Each level of EPI management is dependent upon the effective functioning of the level below it, thus the National level is dependent on the Province 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.

This manual sets out the tasks and responsibilities for each level and illustrates the interdependence of the levels to the whole.

2.3 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 which will ensure availability of potent vaccine at least cost.

Factors to be considered:

| Fast is appropriate for: | Slow is appropriate for: |
|--|--|
| <ul style="list-style-type: none">▪ Unreliable refrigeration at clinic level▪ Weak management at clinic level▪ Cheap and reliable distribution▪ Short distances▪ High vaccine cost | <ul style="list-style-type: none">▪ Reliable refrigeration at clinic level▪ Strong management at clinic level▪ Expensive and less reliable distribution▪ Long distance▪ Low vaccine cost |

3. Procurement

Good immunisation management begins with the estimation of vaccine and related products needed for the service. 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 not used in South Africa because we have an integrated health system and the “supermarket” approach. For information on these estimates, refer to WHO vaccine information).

Common problems

- Vaccine needs are normally estimated at the provincial level using historic data
- Management of vaccines is generally inadequate; there is often no focal person assigned responsibility for monitoring vaccine wastage; and monitoring and control systems are weak.

Vital considerations

- Vaccine producers require accurate vaccine forecasts to provide sufficient quantities to meet demand
- Vaccines are becoming increasingly expensive, particularly new vaccines
- Global capacity for vaccine production is limited.

Advantages of obtaining accurate forecasts of vaccine needs

- More efficient control of immunization 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.

3.1 Estimates based on target population

Defining target groups

The National Programme defines the target group for EPI. The responsibility of the vaccine manager is to indicate the operational implications of any changes that are made to the target group. For example if Td immunisation was to be added to the schedule it would be the responsibility of the operations manager to set out the logistics implications such as increased storage, distribution and handling costs which 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 to record its progress. 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 you think that you are servicing an extraordinary large number of patients from outside your catchment area, adjustments will have to be made as outlined above in refining 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.

Routine vaccination

Where possible use birth registration;

Where this is not possible, consult other authorities e.g. schools, census, local tribal authority estimates, head counts and birth rates tables (current census extrapolation)

Supplementary immunisation Activities (SIAs) {Campaigns, mop-up, catch-up etc}

Consult other authorities e.g. schools, census, local tribal authority estimates, head counts, birth rates table (current census extrapolation)

EPI target population according to immunisation activity

| Target Population | Routine Immunisation | NID – Polio campaigns | Measles Campaigns |
|------------------------------|----------------------|-----------------------|-------------------|
| Children from 0 to 11 months | X | | |
| Children from 0 to 59 months | | X | |
| Children from 9 to 59 months | | | X |

Rough guidelines on calculating target population

| | | |
|---|------------|------------------------|
| Total population of country (most recent figures) | % of total | 41 million inhabitants |
| Children from 0 to 11 months | 2.5 | 1 025 000 |
| Children from 0 to 59 months | 12 | 4 920 000 |
| Pregnant women | 2.5 | 1 025 000 |



3.2 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 (if an 'on demand' policy is followed then sessions are daily)
- Adoption of the revised Opened Multi-Dose Vial Policy {does not affect BCG, measles or yellow fever(private sector only) vaccines}
- Size of vaccine presentation used
- Wastage factor of the vaccine presentation used

Identify session frequency and estimate session size

Use records to determine how often immunisation sessions were actually given

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 which ever 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 which ever 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 which ever 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 other vaccines are supplied in more than one presentation for use in the public sector. In general, single dose presentations are far more costly than their multi-dose counterparts, and should only be used where the use of a multi-dose vial will be more costly due to high wastage. For example, on a mobile route where there will only be two or three children per session presenting for Hepatitis B, it is cheaper to use three single dose vials rather than open a 10 –

dose vial, if the revised Multi-Dose Opened Vial Policy (MDVP) recommends discarding the balance of the vaccine on return to base. Another consideration is the cost comparison between the vial sizes. If a 10-dose vial costs less than the price of two single-dose vials, it might be more cost effective to use the 10-dose vial on the mobile route. The break-even point (see example in the table below) will determine which vial size should be used.

Procedure for selecting presentation:

For which type of clinic is the vaccine intended? (Remember the revised MDVP). Estimate the average number of children that will be attending an immunisation session

Apply the following formula in taking a decision on which presentation should be used.

Cost of the multi-dose vial ÷ number of doses which will be used.

If your answer is greater than the cost of a single-dose presentation, use the single dose presentation.

Selection of presentation for DTP-Hib vaccine

| |
|--|
| <p>For routine service in the clinic – applying the revised MDVP policy.</p> <p>Cost per 10-dose vial = R323.57</p> <p>Cost per single-dose vial = R37.83</p> <p>Doses to be administered = 6 at one session, but remember the opened vial may be used for 7 days after opening, so</p> $323.57 \div 10 = \text{R}32.36$ <p>Therefore 6 doses will cost R194.16</p> $6 \text{ single doses will cost } R37.83 \times 6 = R226.98$ <p>Therefore it is cheaper to use the 10-dose vial</p> |
| <p>For outreach where the vials might be destroyed at the end of the day</p> <p>Cost per 10-dose vial = R323.57</p> <p>Cost per single-dose vial = R37.83</p> <p>Doses to be administered = 6 at one session</p> $323.57 \div 10 = \text{R}32.36$ <p>Therefore 6 doses will cost R195.42</p> <p>6 single doses will cost $R37.83 \times 6 = R226.98$ (less than the cost of the 10-dose presentation)</p> <p>Therefore it is cheaper to use 6 single doses.</p> |

3.3 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 on 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 on 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 |



3.4 Defining supply intervals

The supply interval selected will influence the cost effectiveness of the programme. Too short an interval may increase the cost and create an unrealistic administrative burden. Too long an interval may put the vaccine at risk and result 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 clinics
- Reliability of management at the clinic
- Value of the vaccine stored

Indicative supply intervals for different levels are:

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

3.5 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 DPT, TT, DT, Hepatitis B and OPV vaccines

May be used in subsequent immunisation sessions **for a maximum of one month**, 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;
- If one of these vaccines has a VVM e.g. OPV, the VVM will indicate the potency of the vaccine and the vaccine may be used for any length of time as long as the VVM has not reached discard point, and the other conditions above apply.

Reconstituted vials of DTP-Hib

May be used for 7 days if:

- Each vial is dated when reconstituted
- The vaccines are stored under appropriate cold chain conditions (2 - 8° Celsius with temperature monitoring and recording, measured by the condition of the VVM, if any);
- The expiry date has not passed;
- The vaccine vial septum has not been submerged in water;
- Aseptic technique has been used to withdraw all doses;
- The VVM, if attached, has not reached the 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 six hours, whichever comes first

All opened vials must be discarded immediately if:

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

3.6 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 of following an 'on demand' policy where vaccines are discarded before the optimum number of doses have been administered.

Wastage is calculated as follows:

(Doses issued - doses given) ÷ doses issued x 100 = Wastage (%)

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

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

| Example: Wastage calculation | | |
|---------------------------------------|---|-----------------------|
| Total DTP-Hib vials issued from store | : | 40 vials |
| Doses per vial | : | 20 doses |
| Total doses issued | : | 40 x 20 = 800 doses |
| Doses given: | | |
| DPT-Hib1 | : | 220 doses |
| DPT-Hib2 | : | 210 doses |
| DPT-Hib3 | : | 200 doses |
| Total doses given | : | 630 doses |
| Wastage | : | (800-630)÷800 = 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 opened vial per type for each immunisation point is allowable. This vaccine will be used first in subsequent sessions and should be ignored for any wastage calculations.

Wastage factor

The wastage factor is a numerical value calculated according to the number of doses actually obtainable from a multi-dose vial of vaccine. This factor is calculated for all vaccines and is normally far greater for a vial that must be discarded at the end of an immunisation session.

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

Formula for Calculating Wastage Factor (per dose)

$$\text{Wastage factor} = \frac{1}{1 - \text{Wastage percentage}} .$$

For a 25% wastage

$$\begin{aligned}\text{Factor} &= \frac{1}{1 - 25/100} . \\ &= \frac{1}{0.75} . \\ &= 1.3333\end{aligned}$$

Formula for Calculating Doses Including Wastage

$$100 \text{ Doses incl. wastage} = \frac{100}{1 - \text{wastage percentage}}$$

For 100 doses with a 25% wastage

$$\begin{aligned}\text{Doses required} &= \frac{100}{1 - 25/100} \\ &= \frac{100}{0.75} \\ &= 133.33\end{aligned}$$

The wastage factor for one dose is thus $133.33 \div 100 = 1.33$

Another Method of Calculating Doses Including Wastage

100 doses with wastage of 25%

100 plus 25 = 125 doses

25% wastage on 125 = 31

125 minus 31 = 94 - too few doses

Therefore we need wastage on the 25 i.e. 25% of 25 = 6.25

Plus we need wastage on the 6.25 i.e. 25% of 6.25 = 1.56

plus wastage on the 1.56 i.e. 25% of 1.56 = 0.39

plus wastage on the 0.39 i.e. 25% of 0.39 = 0.1

Add $100 + 25 + 6.25 + 1.56 + 0.39 + 0.1 = 133.3$

The wastage factor for one dose is thus $133.33 \div 100 = 1.33$

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?

$$\begin{array}{r} 100 \times 500 \\ \hline 80 \\ = 625 \text{ doses of vaccine} \end{array}$$

3.7 Supplementary Immunisation Activities {SIAs}(campaigns and special orders)

Vaccine estimates for SIAs are calculated as follows:

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

Example: SIA Vaccine Estimate Calculation

| | |
|--|--------|
| A = Children to be immunised | 60,000 |
| B = Doses per child | 1 |
| C = Uncertainty over size of cohort say 5% | 3,000 |
| D = Anticipated coverage | 90% |
| E = Presentation (in doses) | 10 |
| F = Wastage factor | 1.25 |
| A x B + C D = Doses needed (G) | |
| G x F÷E = Total number of vials required (J) | |
| (60,000 x 1 +3,000x90/100 = 56700 doses | |
| 56700 x 1.25 = 7088 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 40% calculated in routine immunisation.

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

3.8 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)

BCG syringes (fixed needle)

Estimating quantities

- 2ml Syringes: Number of injectable doses to be administered + BCG vials
+10% less stock on hand
- 5ml Syringes: Number of Measles 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 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

3.9 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.

4. Receipt/Dispatch of Supplies

4.1 Vaccines

All Levels



- Delivery to be made to a named person;
- Check delivery is to the correct addressee;
- Check for open or damaged packing or vaccine carrier/cold box;
- If the vaccine has been shipped with cold chain monitor cards (CCM) and/or Freeze Watch indicators(FW) check and record the condition of the cards and FW:

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. If OPV, check the VVM, and do not use if it has reached discard point. Check VVM status of any other vaccines – if no other VVMs - use measles within 3 months and 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 do not use (check VVM status on OPV and any other vaccines), if no VVMs, use DTP, DTP-Hib 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) -0.5°C | Record reading on the shipping document, Accept the shipment, Do not use DTP, DT, TT, Hepatitis B or DTP-HiB vaccine Report immediately to the supplier. |

- 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 | Action |
|---|--|
| Ice packs frozen | Record "ice packs frozen" on the shipping document, if Hepatitis B, DTP-Hib or another toxoid is in the shipment check to see if vaccine has been frozen (Shake test if it has 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, 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. |

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 5.5 for description of VVM)

- Check the quantity and type against the invoice/delivery note;
- Sign the delivery note with any 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 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 (FEFO - First 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 is not to be used because of incorrect shipping place to 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 Other EPI supplies

All Levels

- Delivery to be made to a named person or rank;
- Check delivery is 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;
- 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 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

5.1 Stores organisation

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.

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;

Facilities and Size

There is a detailed guideline on sizing and design of vaccine stores printed by WHO. *WHO Guideline For Establishing Or Improving National, Regional And District Vaccine Stores 1995*, copies of which are available from the Department of Health. See also Appendix 1 for extracts modified for South Africa.

5.2 Stock management

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.

Lead Time: This is the time between placing the order, and receiving the goods at the facility. For a lead-time of less than one week, use this as the lead-time.

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.

Minimum Stock level: This is the stock level that should trigger a reorder of the item. (Safety stock may be included in this level).

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).

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.

Stock records: The means used to record stock. These may include:

- 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.

Storage of Supplies

Example of stock cards for vaccines

Stock Card

Storage of Supplies

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.

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 stock, stock cards and computer records, plus regular random stock reconciliation (audits) should be conducted.

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 HepB vaccine was used monthly, and the lead-time for delivery is 2 weeks, the following is calculated:

$$\begin{aligned} \text{Minimum stock} &= (10 \times 2) + 20 && (\text{consumption period is two weeks (20/2),} \\ &&& \text{lead time is two weeks, and safety stock 20}) \\ &= 40 && \text{The safety stock is lead-time multiplied by the} \\ &&& \text{average consumption in that period} \end{aligned}$$

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:

$$\begin{aligned} \text{Maximum stock} &= 40 + (1 \times 20) && (\text{minimum stock is 40, average} \\ &&& \text{consumption}) \\ &= 60. && 20 \text{ vials per month and procurement} \\ &&& \text{period = 1 month).} \end{aligned}$$

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 heatsensitive pharmaceuticals and medical related items.

| Supply/ Procurement period | Reorder factor for stable items¹ |
|-----------------------------------|--|
| 1 month | 3 |
| 2 months | 5 |
| 3 months | 7 |
| 4 months | 9 |

5.3 Expired or damaged stock

In all facilities, expired stock must be reported as avoidable wastage (See 8.3 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.

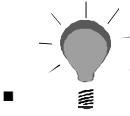
Never use a vaccine that has been stored beyond its expiry date. If vaccines are distributed correctly, each batch received should bear the **same or a later expiry date** than that of the vaccines in the refrigerator of the clinic.

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 district pharmacist.**
 - Report the following data to your supervisor:
 - Duration of the power failure;
 - Temperature inside the refrigerator when the power is reconnected,

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

- 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 these 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 the Board of Survey (see protocol below).

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

Protocol for the disposal of condemned/discharged 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 authority from Pharmaceutical Services** in the 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 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.

Nursing personnel **do not have the authority** to dispose of or to destroy vaccines that have passed expiry date, or reached VVM discard point.

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 DTP-Hib that has been reconstituted for more than 7 days.

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

Shake Test



The Shake Test is designed to determine whether adsorbed vaccines (DPT, DT, Td, TT, Hepatitis B or the DTP diluent of the tetravalent Hib vaccine) have been frozen. 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 until the contents are solid, and then let it thaw. This vial is the control sample. Clearly mark the vial so that it cannot later be used by mistake.

2. Choose a test sample:

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

3. Shake the control and test samples:

Hold the control sample and the test sample together in one hand and shake vigorously for 10-15 seconds.

4. Allow to rest:

Leave both vials to rest.

Compare the vials:

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

Subsequent action:

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

5.3 Guidelines for discarding vaccines (see also section 10.5)

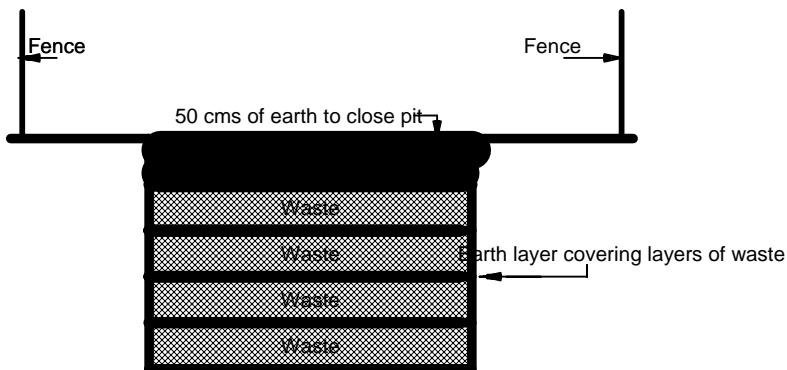
Final disposal/destruction of condemned vaccines

The Board of Survey is 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.
- Where suitable on-site incineration exists, these must be incinerated. If there is no suitable on-site incineration these should be placed in a container marked with black or dark green and returned to a site where they can be incinerated. If no incineration on site 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 site where there is incineration. In the absence of a suitable place for incineration they should be buried in a pit, which has a security fence, and covered immediately with a layer of earth, when full, the pit should be sealed with a minimum of 50cm cover as illustrated below.

Storage of Supplies



Burial should only be used if there is no other option available.
Dumping in the placenta pit is not an approved means of disposal.

5.4 Storage temperatures for vaccines

| Provincial Store | Sub-Provincial Store | Clinic |
|---|---|---|
| Polio and measles 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 and measles 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. |

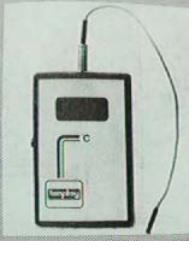
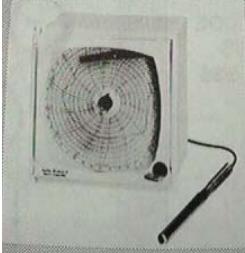
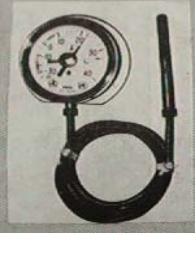
During distribution all vaccines must be transported in insulated containers at a temperature between 2°C and 8°C. Those vaccines that are normally stored frozen may be refrozen after transportation.

5.5 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 dial thermometer or a WHO approved alcohol or mercury thermometer. 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 six months. | Read twice daily, first thing in the morning and last thing in the working day. Keep a 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 working day. Keep a chart for each appliance (See Appendix 3). Charts to be kept for six months |

Examples of suitable equipment are shown in Figure 4

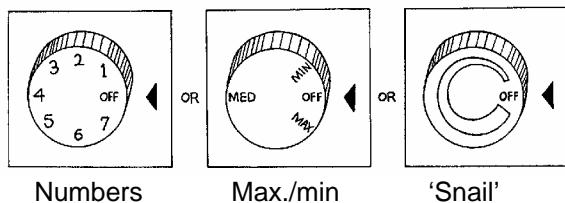
Figure 4
Examples of Temperature Monitoring Equipment

| Province | Sub Province | Clinic |
|---|---|--|
|  |  |  |
| Electronic logger | Electronic Remote sensor | Alcohol/mercury |
|  |  |  |
| Chart recorder | Vapour pressure | Bi-metal dial |

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 5
Examples of thermostat dials



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, this will increase the amount of cooling and thus allow the refrigerator to become cooler.

Stop Watch

In addition to the thermometer the refrigerator at clinic level should be supplied with the Stop Watch. This device combines the CCM indicator with the Freeze Watch and is used to monitor conditions in a refrigerator over 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. (See section 4.1)

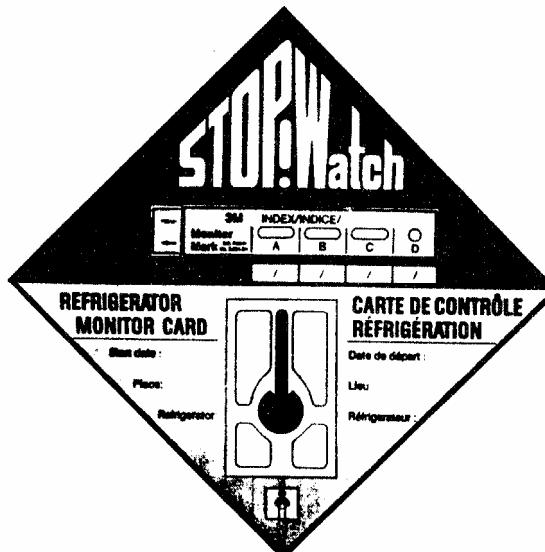


Figure 6: The Stop Watch

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 that the CCM accompanied.

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 there has been and where it occurred. This information may then be used by a supervisor should there be a

Chain Monitor

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.

| Vaccine Cold Chain Monitor | | | | |
|---|-------|----------|----------|-------|
| Date in | Index | Location | Date out | Index |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| 3M INDEX/INDICE /ايندكس 10°C 34°C MonitorMark™ Indicator A B C D | | | | |
| To Activate Fold Up & Pull | | | | |
| If A all blue If B all blue If C all blue If A & B & C & D all blue | | | | |
| TEST VACCINE BEFORE USE | | | | |
| Use within 3 months Use within 3 months Use within 3 months | | | | |
| These vaccines may be used | | | | |
| SUPPLIER FOURNISSEUR Name: _____ Name: _____ Date of dispatch: _____ Date d'expédition: _____ Vaccine: _____ Vaccin: _____ | | | | |

Figure 7: The Cold

Freeze Watch

The **Freeze Watch** (Figure 8) is used to indicate if the refrigerator has reached a temperature when the vaccines will be near to freezing. The Freeze Watch should be placed with the vaccines nearest the evaporator plate in a domestic type refrigerator because these vaccines are the most likely to freeze. If the Freeze Watch breaks, it has been frozen and all of the freeze sensitive vaccines in the refrigerator should be subjected to the shake test to determine which should be discarded and recorded as avoidable wastage. All refrigerators storing vaccines should be supplied with a Freeze Watch indicator unless they are already supplied with a stop watch.



Figure 8: Freeze Watch

Vaccine Vial Monitor (VVM)

VVMs (Figure 9) are attached to all OPV 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.

VVM

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 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.

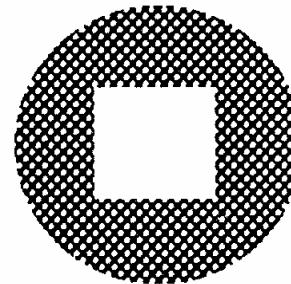


Figure 9:

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.

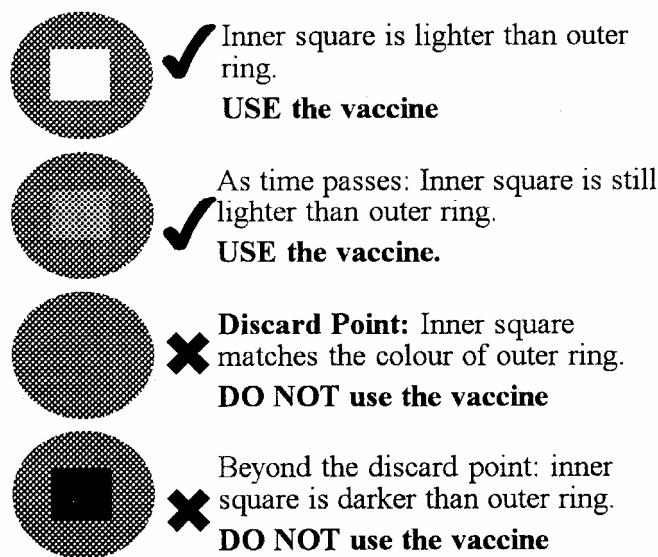
The inner square is initially lighter in colour than the outer circle. It remains so until the temperature and/or the duration of heat reaches a level that is likely to degrade the vaccine beyond the acceptable limit.

At the discard point the inner square is the same colour as the outer circle. 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.

Figure 10 illustrates the VVM readings

Figure 10

Reading a Vaccine Vial Monitor



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.

| Most sensitive to heat | |
|-------------------------|--|
| OPV | |
| Measles | |
| DPT, Yellow Fever | |
| BCG | |
| Hib, DT | |
| Td, TT, HepB | |
| Least sensitive to heat | |

Figure 11: Heat Stability of Vaccines

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. VVM2, which is assigned to OPV, the most heat-sensitive vaccine, reaches its endpoint in 48 hours at 37°C, whereas VVM30 on hepatitis B vaccine, one of the most heat-stable vaccines, takes 30 days to reach its endpoint 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 needs a VVM14.

5.6 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 ('**first expired, first out [FEFO]** 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 immunization 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.

For 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 DPT-Hib, DPT, DT and TT, and Td 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 DTP 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'.

For 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 DTP, DTP-Hib, DT and TT 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 DPT and TT vials.

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.



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 : DTP, TT, hepaTiTis B, Hib Type B, and even diluenT .

| Vaccines | Depot | Sub-depot | | Fixed Clinic | Mobile Clinic | |
|--|---|-----------|----------|--------------|---------------------|--|
| | | Region | District | | | |
| | | 6 months | 3 months | 1 month | 1 month | |
| OPV | -15°C to -25°C | | | | | |
| BCG | 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. | | | | | |
| Measles | | | | | +2°C to +8°C | |
| HepB | | | | | | |
| DTP-Hib | | | | | | |
| DTP | | | | | | |
| DT | | | | | | |
| TT | | | | | | |
| Td | | | | | | |
| <p><i>Diluent vials must NEVER be frozen. When the manufacturer supplies a freeze-dried vaccine packed together with its diluent, ALWAYS store the product 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</i></p> | | | | | | |

5.7 Parenteral Supplies

Estimating storage volume

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 (N) in a period 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
 $50 \times 7 \times 70\% \times (0.05+0.0084) = 14.3\text{Lt. Gross volume.}$

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 |

¹Assumes 7 injections per NBC & 100% coverage.

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. | $90 \times 2\text{ml} + 9 \times 5\text{ml}$ | $60 \times 2\text{ml} + 6 \times 5\text{ml} + 6 \text{ vials}$ |
| 10Lt. | $180 \times 2\text{ml} + 18 \times 5\text{ml}$ | $120 \times 2\text{ml} + 12 \times 5\text{ml} + 12 \text{ vials}$ |
| 20Lt | $360 \times 2\text{ml} + 36 \times 5\text{ml}$ | $240 \times 2\text{ml} + 24 \times 5\text{ml} + 24 \text{ vials}$ |
| 25Lt. | $450 \times 2\text{ml} + 45 \times 5\text{ml}$ | $300 \times 2\text{ml} + 30 \times 5\text{ml} + 30 \text{ vials}$ |

Storage conditions

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

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.

6. Distribution of Supplies

6.1 Packing volumes

Vaccines

The net volume of vaccine and other heat sensitive supplies is shown below:

| Vaccine | Presentation/ Dose/box | Vol./dose ml | Doses/ 20Lt cold box | Vials/ 20Lt cold box |
|------------------|---------------------------|--------------|-------------------------|-------------------------|
| Hep B, | 1 | 2.8 | 710 | 710 |
| Hep B, | 10 | 2.8 | 710 | 71 |
| DTP-Hib1 | 1x10 | 43.2 | 46 | 46 |
| DTP-Hib1 | 10 | 11.9 | 168 | 17 |
| Measles | 1 | 11.3 | 180 | 180 |
| Measles | 10 | 3.0 | 600 | 60 |
| Measles diluent | 10 | 2.4 | 850 | 85 |
| OPV | 10 | 2.5 | 760 | 76 |
| OPV | 20 | 1.5 | 1,300 | 65 |
| BCG ² | 20x10 | 1.0 | 2,000 | 100 |
| DTP | 10 | 3.0 | 600 | 60 |
| DTP/DT/TT | 20 | 2.5 | 760 | 38 |

A WHO document on the Vaccine Volume Calculator gives greater detail on the different products available. It includes two spreadsheets in Excel format for use in calculating storage space needed for the introduction of new vaccines into the EPI programme. A copy of the document is included in Appendix 4, and the electronic document can be downloaded for use from the WHO website at <http://www.who.int/vaccines-access/Newdocuments.html>

Other Heat Sensitive Supplies

| Vaccine | Presentation (doses) | Vol./dose ml | Doses/ 20Lt cold box | Vials/ 20Lt cold box |
|----------------|-------------------------|--------------|-------------------------|-------------------------|
| Yellow Fever | 1 | 84.0 | 238 | 240 |
| Rabies | 1 | 84.0 | 238 | 240 |
| Rapid RH test | 50 tests | 34.7/test | 590 tests | 590 tests |
| Rapid RH test | 250 tests | 13.9/test | 1,450 tests | 1,450 tests |
| Immunoglobulin | 1 | 57 | 350 | 350 |
| Insulin | 10 ml | 0.8/ml | 2,500 x 1ml | 250 |
| Insulin | Penfill | 3.5/ml | 580 x 1ml | 58 |
| Oxytoxin | 5 | 27.2 | 75 | 15 |

² Includes diluent

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 |

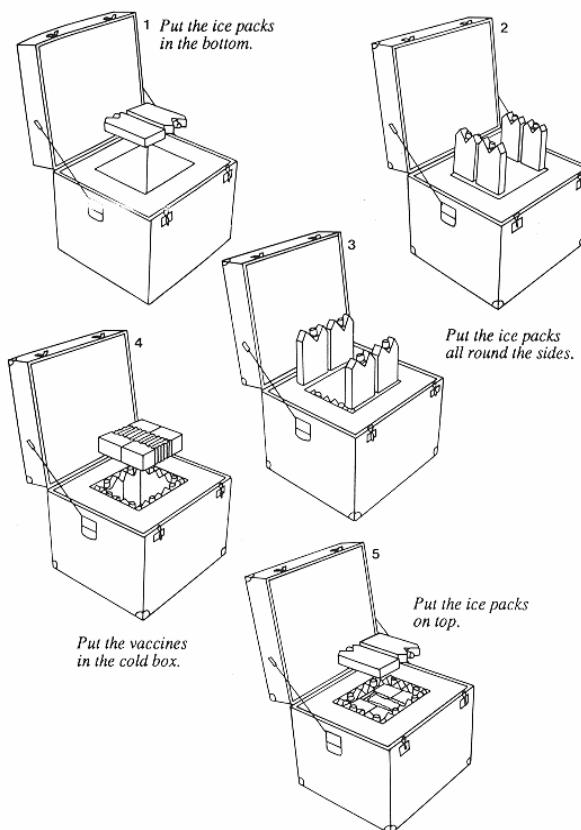
6.2 Packing procedures for vaccines and diluent

Insulated packing must protect all vaccine during distribution. Packing for distribution should comply with WHO or RSA standards. 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.

Cold Box/Transport Box Packing

Figure 12 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 12
Preparing a cold box for vaccine shipment from a depot





The following steps are illustrated in Figure 12:

1. Fully condition the ice packs before needed. To condition frozen ice packs remove them from the freezer and allow to stand 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 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) in the box on top of the vaccine
6. Cover the vaccines with some more conditioned ice packs.
7. Close the lid.

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.



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 vaccine and underneath the ice packs.
5. CCMs that arrive from the supplier should be stored with the vaccine 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 power breaks.

Use of cold packs instead of frozen packs

Research has recently been conducted on the use of cold packs instead of frozen ice packs in transporting vaccines. The results to date 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.

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 | 1. If a clinic is to collect its vaccine: Follow the procedure for outreach. If the clinic has | Prepare a WHO or RSA approved vaccine carrier or cold box following the method shown in Figure 6. |

| Depot to Sub-depot/district | Sub-depot to Clinic | Clinic to Outreach |
|---|--|--|
| <p>cold box or transport box plus sufficient ice packs. If the sub-depot does not have sufficient frozen ice packs they may exchange theirs with those at the Provincial store, cold for warm.</p> <p>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.</p> | <p>a problem freezing sufficient ice packs these may be exchanged, cold for warm, at the sub-province depot.</p> <p>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.</p> | <p>If an activated CCM is to be used place it in the carrier or box, otherwise place a thermometer in the carrier or box</p> |

6.3 Transport/delivery procedures

Transport selection, (options)

| Supplier to Province | Province to Sub Province | Sub-Province to Clinic |
|---|---|---|
| Delivery | Delivery | 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 | | |
| Own Delivery | Own Delivery | Own Delivery |
| Advantages | Advantages | Advantages |
| -Fully controllable -May cost less -Can be combined with other duties -Programme monitoring easier. -Possible to introduce a delivery | -Fully controllable by supplying store -May cost less -Can be combined with other duties -Programme monitoring easier. | -Fully controllable by supplying store -May cost less -Can be combined with other duties -Programme monitoring easier. |

Distribution of Supplies

| Supplier to Province | Province to Sub Province | Sub-Province to Clinic |
|---|---|--|
| circuit serving a number of locations. | -Possible to introduce a delivery circuit serving a number of locations. | -Possible to introduce a delivery circuit serving a number of locations. |
| Disadvantages | Disadvantages | Disadvantages |
| -Cost variable -Requires health authority to have more infrastructures. -Vehicle availability often problematic | -Requires health authority to have more infrastructure -Takes more time for supplier -Vehicle availability often problematic | -Requires health authority to have more infrastructure -Takes more time for supplier -Vehicle availability often problematic |
| Collection Advantages | Collection Advantages | Collection Advantages |
| -Controlled by the recipient -Can combine with other activities | -Controlled by the recipient -Can combine with other activities | -Controlled by the recipient -Can combine with other activities |
| Disadvantages | Disadvantages | Disadvantages |
| -May be more expensive. -May take more time -Requires more infrastructure at the sub-depot -Vehicle availability often problematic | -May be more expensive. -May take more time -Requires more infrastructure at the sub-depot -Vehicle availability often problematic | -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.

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 Thursday or Friday.



Receipt procedures

On receipt the receiving store checks:

- Number of parcels delivered;
- Quantity delivered against requisition placed;
- Quantity delivered and charged against delivery note;

Distribution of Supplies

- Condition of CCM or ice packs;
 - Condition of the VVMs;
- then:
- Places vaccine in cold storage;
 - Enters 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.

7. Cold Storage and Distribution Equipment

7.1 Cold Rooms

See Appendix 1 for:

Sizing, (option cold room or refrigerators)

Options, selection criteria

Care and Management includes temperature monitoring

Maintenance

7.2 Refrigerators and Freezers

Sizing

| Estimating Storage Volumes | | |
|--|---|--|
| Provincial depot | Sub-depot/district | Clinic |
| <p>+2°C to +8°C capacity</p> <p>Total number of doses of BCG, DTP, Hepatitis B, DTP-HiB requested in the supply period by the sub-stores x 113 /1000 + total number of Hepatitis B and DTP-HiB single dose requested by the sub-stores in the supply period x 575/1000 = Gross litres of refrigerated storage</p> <p>-20°C freezer capacity</p> <p>Total number of OPV and measles doses requested in the supply period x 13/1000 + total number of single dose measles requested in the supply period x 10/1000 = Gross freezer volume for vaccine.</p> <p>Ice Pack freezing</p> <p>Vaccine collected:</p> <p>Total number of sub stores collecting in a 24 hour period x 15 = Number of litres of freezer volume required.</p> <p>Vaccine delivered:</p> <p>Total number of 20 Lt cold boxes used in a 24 hour</p> | <p>+2°C to +8°C capacity</p> <p>Total number of doses of BCG, DTP, Hepatitis B, DTP-HiB used in the supply period by the clinics served x 113 /1000 + total number of Hepatitis B and DTP-HiB single dose used by the clinic served in the supply period x 575/1000= Gross litres of refrigerated storage</p> <p>-20°C freezer capacity</p> <p>Total number of OPV and measles doses issued in the supply period x 13/1000 + total number of single dose measles issued in the supply period x 10/1000 = Gross freezer volume for vaccine.</p> <p>Ice Pack freezing</p> <p>Vaccine collected:</p> <p>Total number of clinics collecting in a 24 hour period x 3 = Number of litres of freezer volume required</p> | <p>See Table below for clinics serving up to 40,000 people.</p> <p>Allow 4 Lt. per vaccine carrier used for collecting vaccine plus the quantity shown in the table below for mobile activities.</p> |

| Estimating Storage Volumes | | |
|---|--|---------------|
| Provincial depot | Sub-depot/district | Clinic |
| period x 15 = Lt of ice pack freezing required. | Vaccine delivered: Total number of 10 Lt cold boxes used in a 24 hour period x 10 = Lt of ice pack freezing required. | |

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

| Catchment Population | Volume (Lt.) |
|----------------------|--------------|
| =<10,000 | 16 |
| >10,000- 20,000 | 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

| Catchment Population | Volume (Lt.) per Number of Mobile Sessions per week ¹ | | | | |
|----------------------|--|------------|------------|------------|------------|
| | 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 equipment²

| 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 | 8 0Lt refrigerator with 30 Lt of freezer capacity |

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

Options, upright or chest, compression or absorption selection criteria

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.

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. The Pharmaceutical Society of South Africa in Pretoria has a selection of suitable chest and upright fridges available in South Africa on display in their offices in Pharmacy House, De Veer Street, Arcadia, Pretoria. A price list may be obtained from them. Telephone - 0123010820.

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.

As the price of vaccines rise, the importance of selecting high quality equipment increases. Each dose of DTP-Hib vaccine is worth more than R20.00, and to lose a fridge full of EPI vaccines as a result of a power failure over a weekend could be very costly.

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 morning and afternoon and adjust the thermostat if necessary.

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

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

Weekly Tasks

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



Monthly Tasks

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)

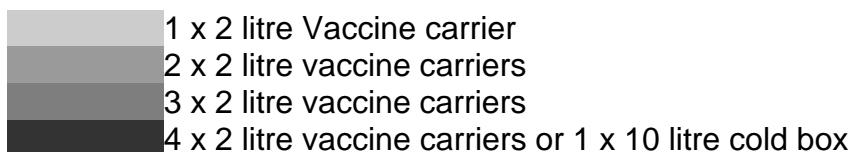
Clean the condenser coil on the back of the refrigerator and dust round the compressor.

7.3 Cold Boxes and Vaccine Carriers

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 |
| Population | 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 |



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

Options, 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-life (more than 5 days) | medium life (1-5 days) | short 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 |

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 at once. When cleaning specifically check the lid gasket, because any damage to the gasket will seriously shorten the cold life.

7.4 Maintenance of cold chain equipment

Cold Rooms,

When this equipment is purchased, recommended spares should also be bought and held in the stores, or the suppliers should be asked to offer a maintenance contract whereby they routinely service the cold rooms once a year.

Refrigerators, Freezers

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

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

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.

Note: The final date for conversion from the old gases to CFC-free gases in equipment is end 200.

8. Specimen Collection and Cold Chain

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, on hand into which the specimen will be placed. **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 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 to ensure a successful virological examination and correct disease diagnosis to be made.

9. Records and Reporting

9.1 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 newborns / children < 1 year of age, per year (target population);
- 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;

9.2 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:
- Number of live births;
- 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.

9.3 Data analysis

Wastage

Avoidable wastage:

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

Unavoidable wastage:

- wastage due to the immunisation policy
- unused vaccines 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.

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), 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.

10. Management of Sharps

10.1 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 & incineration of the syringes & needles in the disposal box and maintain records of disposal and destruction

NEVER recap a used needle with both hands

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."

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."

Section 5.2.2

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

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.

10.2 Estimating volume of used sharps

Routine Services

- (a) Estimate the number of 5 litre containers of syringes used by 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 | Crude Birth Rate | | | | | |
|----------------------|---|----|----|----|----|----|
| | 10 | 15 | 20 | 25 | 30 | 35 |
| | Number of 5 litre disposal boxes per month for 100% immunisation coverage | | | | | |
| 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 used ÷ 100

Number of 5ml used ÷ 60

Number of 10ml 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, $300 \times 2\text{ml} + 240 \times 5\text{ml} + 40 \times 10\text{ml}$

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
 $12 \div 2 = 6$ hours of incineration time per month to burn the sharps.

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 $A \times 50 \div 1000 =$ Total volume in litres.

C= Number of sharps boxes required to hold used sharps

For 5 litre boxes $B \div 5$

For 10 litre boxes $B \div 10$

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 $E=C \div D$

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

A= 1,894,362

B= $1,894,362 \times 50 \div 1,000 = 94,718$ Litre. of sharps waste

C = $94,718 \div 5 = 18,944$

Incinerator is rated at 220Kg per hour

D= 30

E = $18,944 \div 30 = 631$ hours burning time

10.3 Disposal procedures

Disposal of sharps should be in accordance with the SABS Code 0248:1993 in specific non-PVC sharps containers clearly marked “SHARPS”.

Section 5.6

“The health care facility shall dispose of all waste in accordance with national, provincial, regional and municipal regulations and legislation.”

If on site incineration is available no full sharps box should be kept for more than 1 week before it is destroyed.

If there is no on site incineration no full sharps box will be kept in a health facility for more than 4 weeks before disposal for destruction.

10.4 Destruction/final disposal procedures

SABS Code 0248:1993 Section 8.4.1

“Filled sharps containers shall be treated or handled or disposed by any of the following methods. The preferred method is on-site incineration. Other methods outlined below may be chosen by health care facilities, based on the individual facility’s experience and local conditions. In all cases, disposal shall comply with national, provincial, regional and municipal regulations and legislation.”

On-site:

“Incineration decontaminates and renders sharps unusable. The sharps containers shall be made of a material suitable for incineration.”

“Removal and handling of the ash from the incinerator may pose a physical hazard to personnel through scrapes and puncture wounds from the remaining portion of the sharps”

Off-site

Section 5.5.3 “Waste containers shall be moved only when properly closed”

Section 5.5.4 “Specific routes for the movement of waste shall be planned in order to minimise its passage through patient care areas and other clean areas”.

“Off-site incineration has the same benefits and risks outlined in 9.5.1 above”.

“Additional exposure risk is incurred through increased handling in transportation and exposure to the environment in a transportation accident causing container rupture”

New technology

“the above methods take into account existing technology and handling methods. New handling and disposal methods may be considered by facilities as they arise and are approved by national, provincial or municipal governing bodies.”

Commercial contractors

If a private contractor is employed to provide a service, it should include the distribution, collection and destruction of all sharps boxes

Hazardous plastics

SABS Code 0248:1993 Section 5.1 Note

“It is recommended that plastics materials that are to be included in the stream of waste to be incinerated be non-halogenated. Materials bearing heavy metals should not be used. The most commonly used plastics, polyvinyl chloride (PVC), and yields hydrogen chloride upon incineration. Examples of non-halogenated plastics include polystyrene, polyesters and polyolefins such as polyethylene and polypropylene.”



Plastic containers which are not specifically designed to be incinerated should not be used as sharps boxes. Sharps boxes must be purpose designed, either from cardboard or plastic which are safe to burn.

Records

All facilities generating waste will maintain records of the waste produced in such detail that the individual sharps box can be identified. The records will include:

For on site destruction:

- Number of sharps boxes filled by box size and date of filling
- Number destroyed
- Date of destruction
- Signature of responsible person

For off site destruction either by commercial company or hospital:

- Number of sharps boxes filled by box size and date of filling
- Number sent for destruction by box size and date
- Signature of responsible person

At incineration sites

- Number of sharps boxes received by box size and date of receipt
- Date of destruction
- Signature of responsible person.

11. Contingency Plans

11.1 Power failure

| Provincial Depot | Sub Depot | Clinic |
|--|---|---|
| <p>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.</p> | <p>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.</p> | <p>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 the clinic/health centre for the event of power failures. Possible alternative short term storage at nearby stores/businesses/homes should be sought.</p> |

11.2 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 request the vaccine suppliers for emergency replacement and explain the reason. 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 request the Provincial depot for emergency replacement and explain the reason. 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 request the Sub depot for emergency replacement and explain the reason. Any stock shortages should be reported to the supervisor immediately. |

11.3 Sudden demand

| Provincial Depot | Sub Depot | Clinic |
|--|--|---|
| If there is an outbreak of an immunisable 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 immunisable 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 an immunisable 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. |

12. Audit

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:

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.

Appendix 1

Provincial Cold Store

Planning cold rooms

The information in this section assumes the use of prefabricated cold rooms with twin packaged refrigeration units front mounted. 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.

Sizing cold rooms

Algorithm: For each group of vaccines (-20°C 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

Indicative cold room volumes for vaccine supplied in 1994 plus Hepatitis B and HiB which is assumed to be in the same quantities as Hepatitis B estimates for 1995.

| Province | NBC | Storage Volume in M ³ | |
|---------------|---------|----------------------------------|--------|
| | | -20deg C | +4degC |
| Northern | 186,618 | 30 | 40 |
| Mpumalanga | 117,804 | 20 | 25 |
| Gauteng | 122,972 | 20 | 30 |
| North West | 124,457 | 20 | 30 |
| Free State | 94,204 | 15 | 20 |
| KwaZulu Natal | 273,292 | 40 | 60 |
| Northern Cape | 52,139 | 8 ¹ | 11 |
| Eastern Cape | 189,436 | 30 | 40 |
| Western Cape | 86,898 | 15 | 20 |

1. Cold room not justified

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

Cold rooms for vaccine storage should not exceed 2.2 metres internal height. This height limit ensures that vaccine on the top shelf is 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.

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 (+25°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.

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.

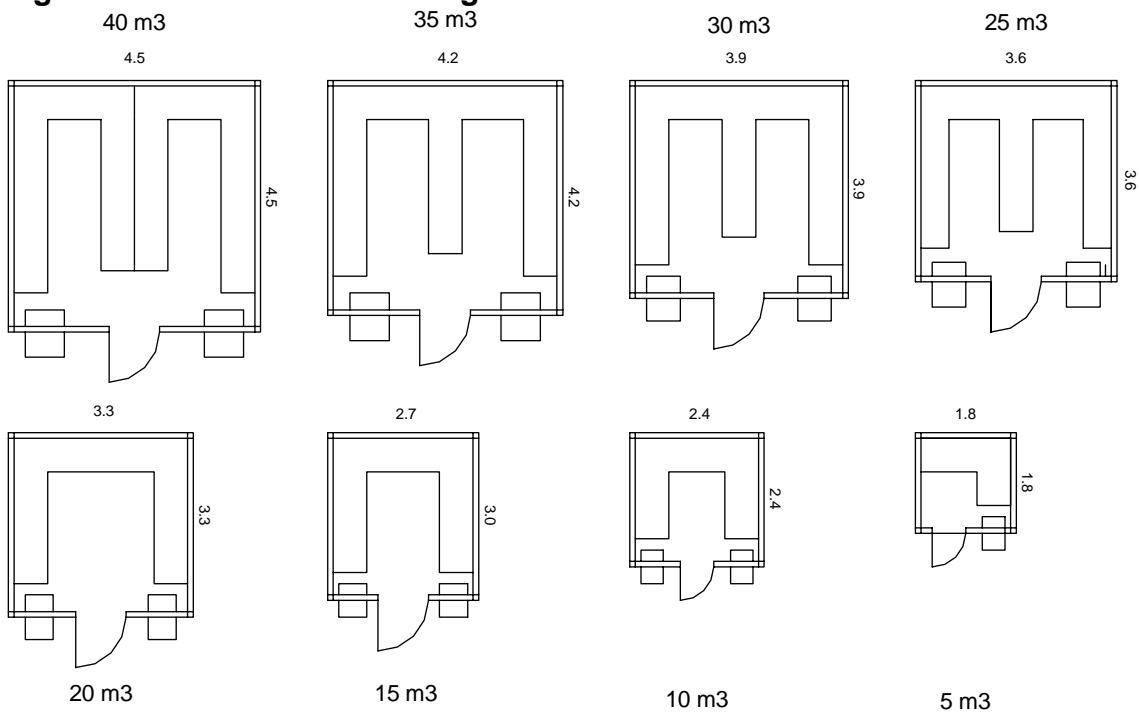
Calculating icepack freezing capacity

Vaccine has to be kept cold during transport. Vaccine 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.

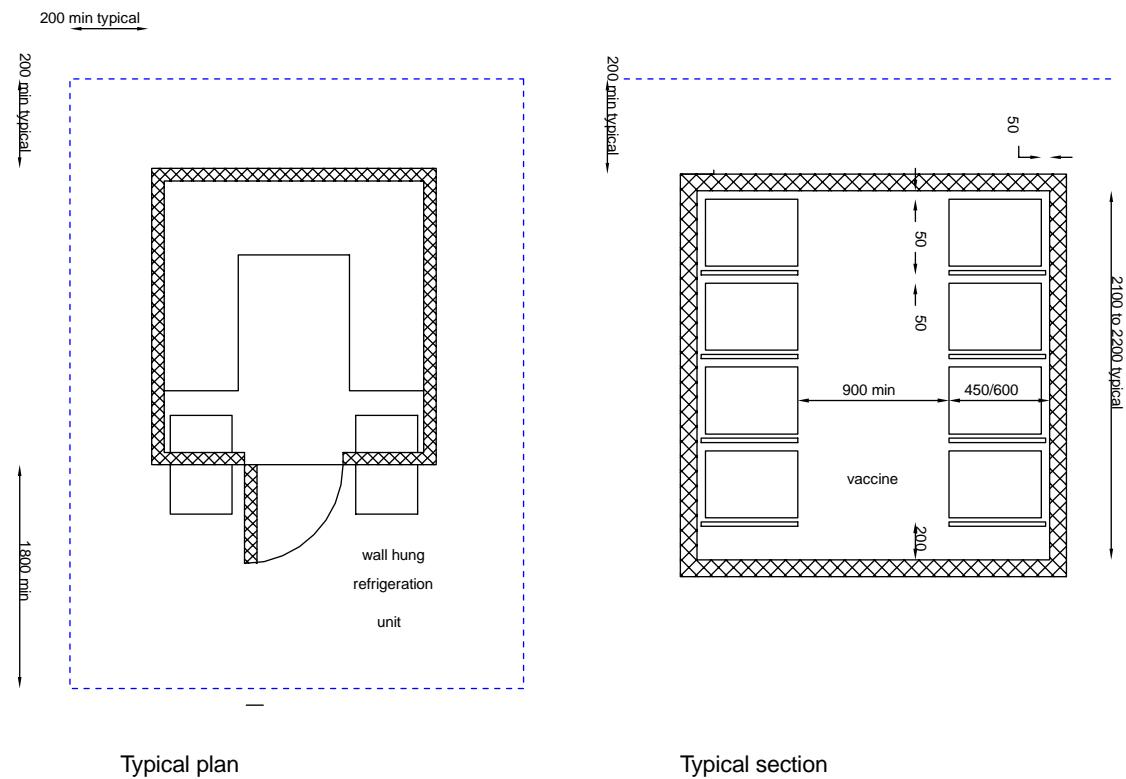
The icepack freezing capacity required depends upon the chosen vaccine distribution strategy. This brief assumes that the provinces will be supplied monthly and that the supply will be spread evenly over the month. Such a policy will maximize the merit of the national store by reducing to a minimum the 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.

Appendix 1

Figure A1: Cold Room Planning and Dimensions



Typical cold room dimensions (internal height 2.2 metres)

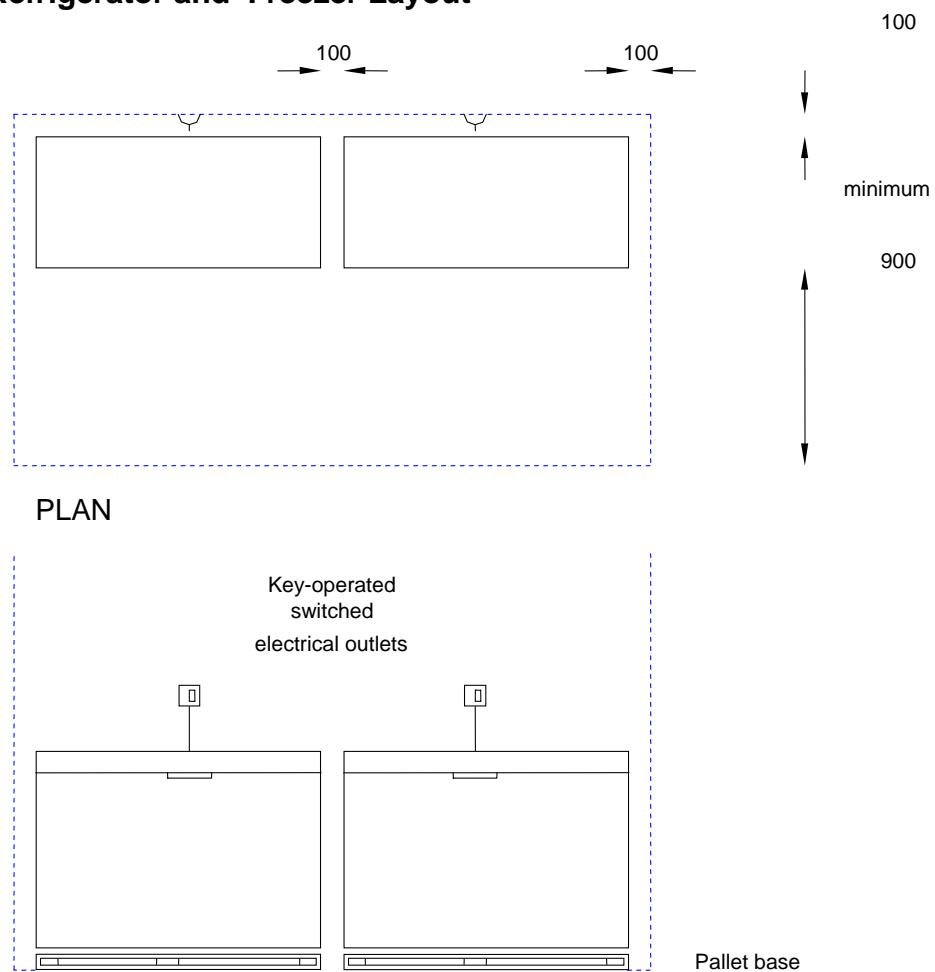


Typical plan

Typical section

Appendix 1

Figure A2: Refrigerator and Freezer Layout



Notes:

- 1) For estimating purposes allow 1.5 m^2 of floor area for every 100 litres of vaccine. The room volume should not be less than 4.5 m^3 per 100 litres of vaccine.
- 2) Provide permanent ventilation at high level.

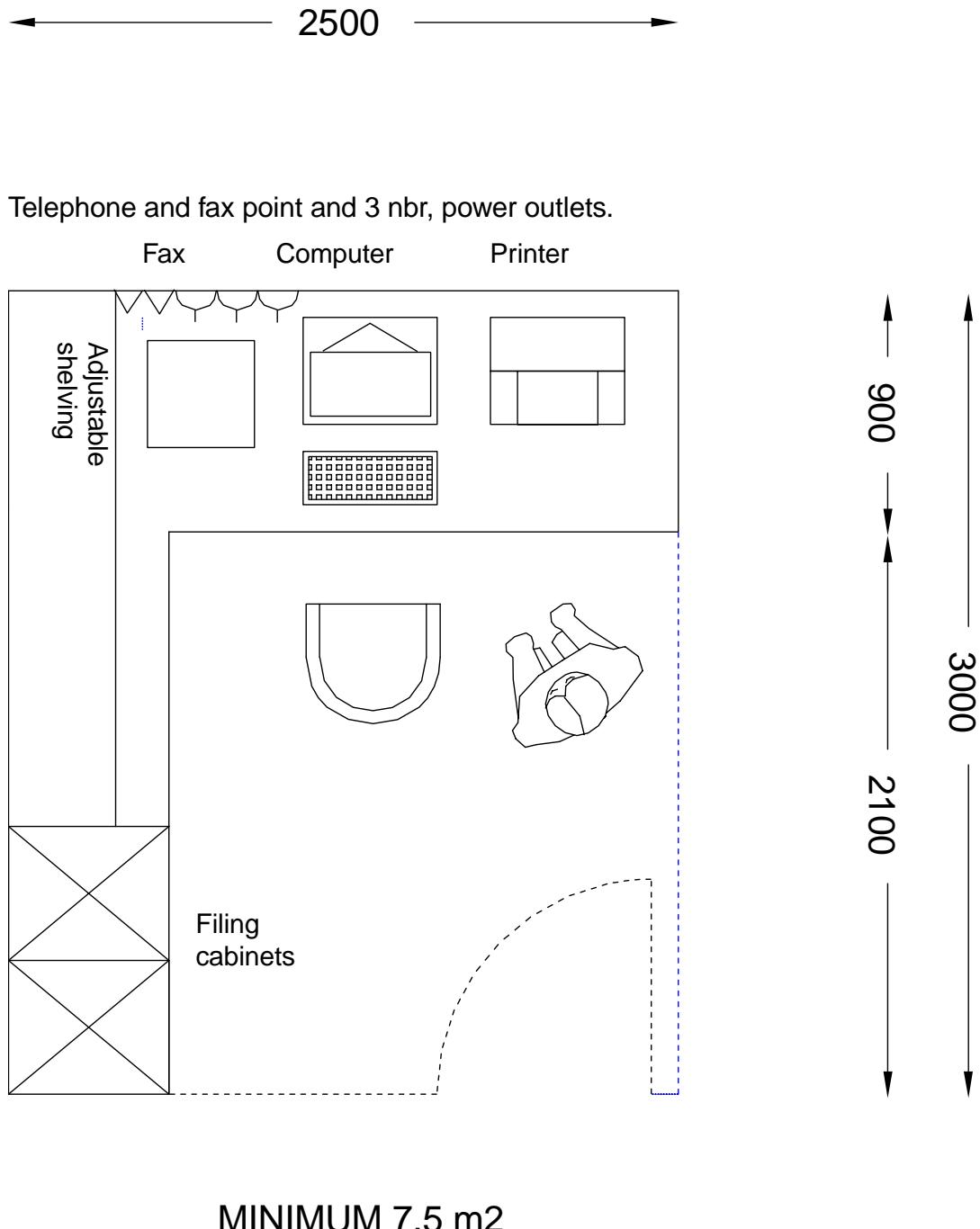
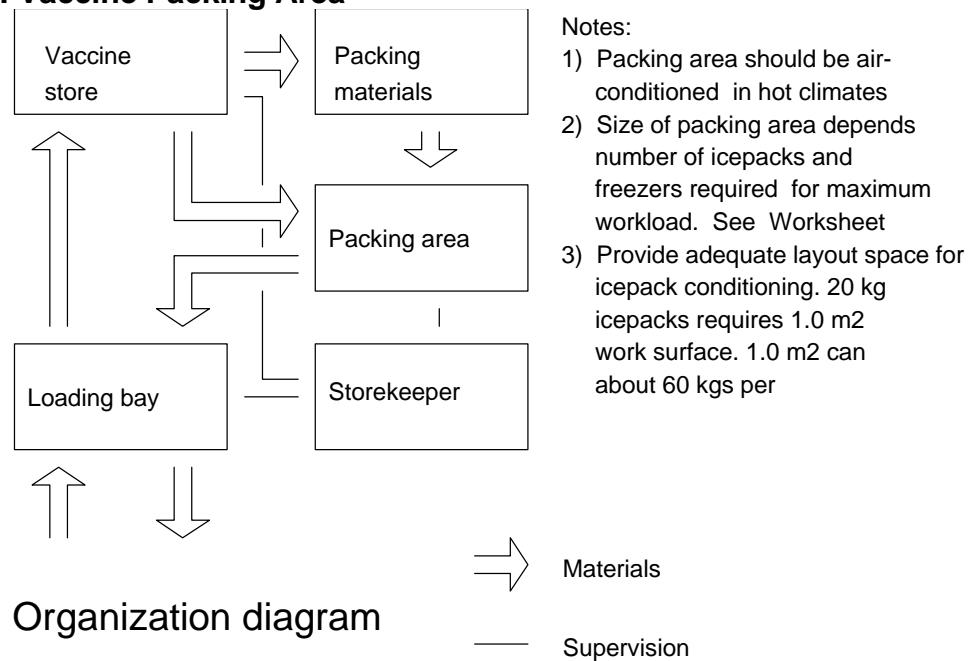
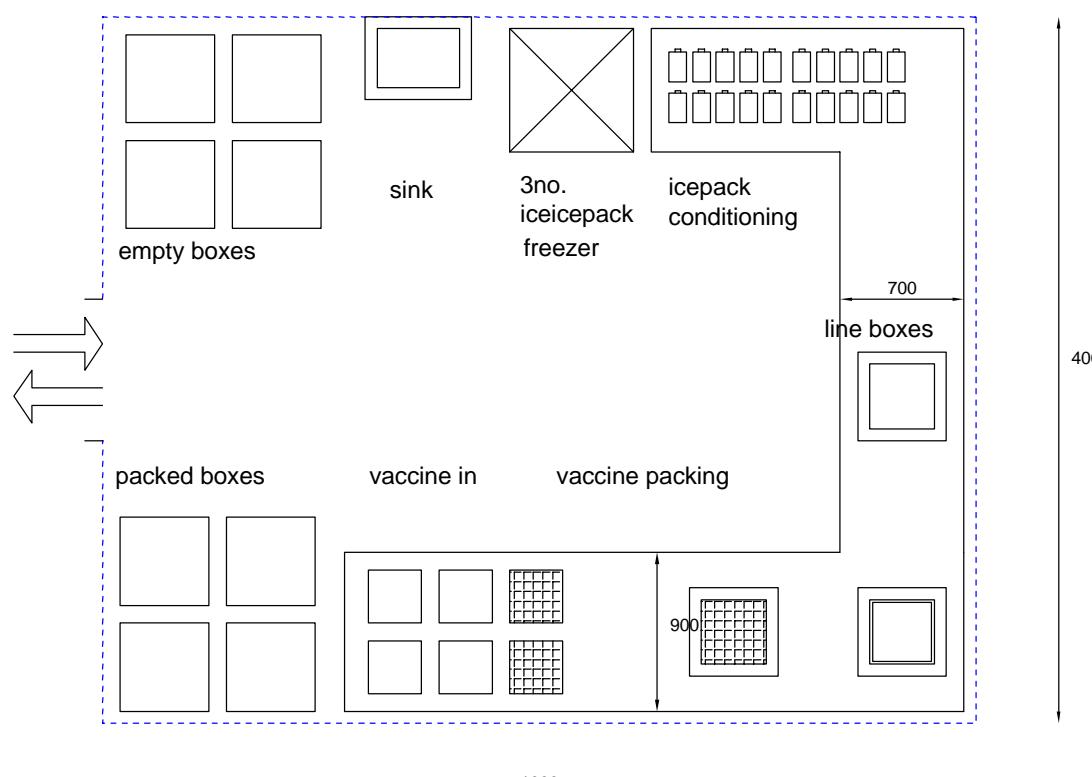
Figure A3: Storekeeper's Office

Figure A4: Vaccine Packing Area



Organization diagram



Layout of a 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.

5 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.

6 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.

7 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.

8 Vehicle loading bays

The detailed design of vehicle loading bays is governed by the size and type of vehicle used. The following matters 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, such as Hepatitis B and DTP-Hib, 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 kept.
- c) **Weather protection:** Loading bays should have a projecting canopy to protect the workers, the vehicle and the vaccine 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.

9 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 store and the size of delivery vehicles.
- 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 the year round?
 - Is there adequate vehicle access and parking space?

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?
-

10 Power Factors

10.1 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.

10.2 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 world stocks are limited. Emergency replacement from a finite world stock also disrupts the supply of vaccine 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.

10.2.1 Generator sizing and selection

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

10.2.2 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.

10.2.3 Generator Siting, 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.

10.2.4 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.

10.3 Voltage Stability

Voltage fluctuations greater than $\pm 15\%$ 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 stabilisers required.

11 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 and level 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 $\pm 3\text{mm}$ 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. 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.³

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 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 the height of the rainy season.

Pests/Vermin

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

³ 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 with 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 $0.065 \times$ the floor area of the store in square metres, but not less than 26A.

Appendix 1

Security

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

Room by Room Schedule

| Number | Room Title | Remarks | Net area m ² | Number of units | Total net area m ² |
|-------------------|-------------------------|---|----------------------------|-----------------|----------------------------------|
| 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 | | | | | 17 |
| | | | | | Gross Area 98 |

Appendix 2**Job Description****National Cold Chain and Vaccine Manager****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 nationally becomes more efficient and cost effective.

- 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 the 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
Family and social contacts

Most Challenging Part of Your Job

Training Requisites

Visual Basic
Access & advanced access
Project Management
MS Project
Managing people
e-logistics
MEDSAS
Writing business plans

Job Description Agreement

We the undersigned agree that the content of the job description is feasible and will enable the job holder to commit him/herself to perform the stated duties to the best of his/her abilities in order to measure the success of this Sub-Directorate in achieving the known objectives during the current period. This will also signify the commitment of the Supervisor to provide the incumbent with the necessary support and authority to perform his/her duties optimally.

Chief Pharmacist

Deputy Director Date:
Date:

Appendix 3

Appendix 3

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 |
| 22 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 20 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 18 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 16 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 14 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 12 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 10 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 0 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| -2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| -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 there a spare gas cylinder? Is there 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

Appendix 4

Vaccine storage capacity calculator

| Vaccine product | No. of doses per vial | Packed volume per dose cm3 | Packed volume per vial cm3 | Source of figures on packed volumes | No of vials in stock | No of vials on order | Net storage volume* in cm3 for vaccines in stock | | | Net storage volume* in cm3 for vaccines on order | | | Net total storage volume* in cm3 for vaccines | | |
|------------------------------------|-----------------------|----------------------------|----------------------------|-------------------------------------|----------------------|----------------------|--|---------|------------|--|---------|------------|---|---------|------------|
| | | | | | | | At +4C | At -20C | All temps. | At +4C | At -20C | All temps. | At +4C | At -20C | All temps. |
| A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P |
| BCG freeze dried | 10 | 1.0 | 10.0 | WHO recommended max. | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| BCG freeze dried | 20 | 1.0 | 20.0 | WHO recommended max. | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Diphtheria-Tetanus-Pertussis-(DTP) | 10 | 3.0 | 30.0 | WHO recommended max. | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Diphtheria-Tetanus-Pertussis-(DTP) | 20 | 2.5 | 50.0 | WHO recommended max. | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Diphtheria-Tetanus | 10 | 3.0 | 30.0 | WHO recommended max. | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Diphtheria-Tetanus | 20 | 2.5 | 50.0 | WHO recommended max. | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Tetanus-Diphtheria | 10 | 3.0 | 30.0 | WHO recommended max. | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Tetanus-Diphtheria | 20 | 2.5 | 50.0 | WHO recommended max. | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Tetanus toxoid | 10 | 3.0 | 30.0 | WHO recommended max. | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Tetanus toxoid | 20 | 2.5 | 50.0 | WHO recommended max. | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Oral polio | 10 | 2.5 | 25.0 | WHO recommended max. | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Oral polio | 20 | 1.5 | 30.0 | WHO recommended max. | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Measles freeze dried | 1 | 9.3 | 9.3 | Aventis Pasteur | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Measles freeze dried | 10 | 3.0 | 30.0 | WHO recommended max. | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Measles-Rubella freeze dried | 10 | 3.0 | 30.0 | WHO recommended max. | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Measles-Mumps-Rubella freeze dried | 10 | 3.0 | 30.0 | WHO recommended max. | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |

Appendix 4

| | | | | | | | | | | | | | | | |
|---|----|-------|-------|-----------------------------------|--|--|----------|--|----------|----------|--|----------|----------|--|----------|
| Yellow Fever | 10 | 3.0 | 30.0 | WHO recommended max. | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Japanese Encephalitis with diluent | 1 | 60.0 | 60.0 | Biken | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Japanese Encephalitis with diluent | 10 | 15.0 | 150.0 | Biken | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Japanese Encephalitis without diluent | 10 | 8.1 | 81.0 | Biken | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Hepatitis B | 1 | 14.9 | 14.9 | Merck & Co. | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Hepatitis B | 1 | 9.7 | 9.7 | GlaxoSmithKline | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Hepatitis B + AD syringe | 1 | 9.7 | 9.7 | GlaxoSmithKline | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Hepatitis B | 2 | 4.8 | 9.6 | GlaxoSmithKline | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Hepatitis B | 6 | 3.2 | 19.2 | GlaxoSmithKline | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Hepatitis B | 10 | 3.0 | 30.0 | GlaxoSmithKline | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Hepatitis B UniJect | 1 | 24.6 | 24.6 | P.T. Bio Farma (Persero) | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Hib liquid | 1 | 32.3 | 32.3 | Chiron | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Hib liquid | 10 | 13.8 | 138.0 | Chiron | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Hib liquid | 10 | 9.5 | 95.0 | Wyeth | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Hib freeze dried | 1 | 9.7 | 9.7 | GlaxoSmithKline | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| DTP-HepB (2 separate vials, but packed together) | 10 | 8.2 | 82.0 | Green Cross Vaccines Co-operation | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| DTP-HepB + AD syringe (2 separate vials, but packed together) | 2 | 41.2 | 82.4 | Green Cross Vaccines Co-operation | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| DTP-HepB combined | 1 | 9.7 | 9.7 | GlaxoSmithKline | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| DTP-HepB combined | 10 | 3.0 | 30.0 | GlaxoSmithKline | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| DTP-Hib combined freeze dried** + AD syringe | 1 | 154.0 | 154.0 | Aventis Pasteur | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| DTP-Hib combined freeze dried** | 10 | 11.9 | 119.0 | Aventis Pasteur | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| DTP-Hib combined liquid | 1 | 32.3 | 32.3 | Chiron | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| DTP-Hib combined liquid | 10 | 13.8 | 138.0 | Chiron | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| DTP-HepB + Hib combined*** | 2 | 9.7 | 19.4 | GlaxoSmithKline | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| DTP-HepB + Hib combined*** | 10 | 5.3 | 53.0 | GlaxoSmithKline | | | 0.0 | | 0.0 | 0.0 | | 0.0 | 0.0 | | 0.0 |
| Net storage volume in cm³ for vaccines in stock, on order and total | | | | | | | 0 | | 0 | 0 | | 0 | 0 | | 0 |
| Net storage volume in litres for vaccines in stock, on order and total | | | | | | | 0 | | 0 | 0 | | 0 | 0 | | 0 |
| Net storage volume in m³ | | | | | | | 0 | | 0 | 0 | | 0 | 0 | | 0 |

Appendix 4

* Net storage volume includes primary packaging but not secondary packaging, nor insulated packaging, nor air circulation space needed to refrigerate vaccines.

** One vial DTP liquid + one vial Hib freeze dried (Hib is reconstituted with the DTP)

*** One vial DTP-Hep.B liquid + one vial Hib freeze dried (Hib is reconstituted with the DTP-HepB)

WARNING! Do not enter data in calculated (blue coloured) cells!

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