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WHO-UNICEF Effective Vaccine Store Management Initiative:

Modules 1–4

Immunization, Vaccines and Biologicals

World Health Organization

unicef

WHO/IVB/04.16–20
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Module 1: Ten global criteria for effective vaccine store management (WHO/IVB/04.17)
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Contents

Course components:

Acknowledgements

The WHO-UNICEF Effective Vaccine Store Management (EVSM) initiative was developed through a step by step consultative and testing process.

Efforts started in December 2001, bringing together 18 experts in this field from all regions of the world and various organizations including the World Health Organization (WHO), United Nations Children's Fund (UNICEF), the Programme for Appropriate Technology for Health (PATH), independent consultants and representatives of national immunization programmes. Over the months, this initial group was further developed into a smaller committee and consisted of the following individuals: Birhan Altay (Ministry of Health, Turkey), Fabian Cenko (Ministry of Health, Albania), Andrew Garnett (freelance consultant, United Kingdom), Stephane Guichard (WHO SEARO, India), Umit Kartoglu (WHO HQ, Switzerland), Mikko Lainejoki (UNICEF SD, Denmark), John Lloyd (PATH Europe, France), Denis Maire (WHO EURO, Denmark), and Soren Spanner (UNICEF SD, Denmark).

During the preparation of the package Modules 1 to 4 were presented and discussed at the following meetings: Regional immunization programme managers meetings in Cape Town (2002), Vienna (2002), Casablanca (2002); GAVI Regional Working Group meeting in Cairo (2003); WHO-UNICEF-PATH Technology and Operations Panel (2003); and TechNet21 Antalya consultation (2004). The document was also extensively reviewed by all WHO and UNICEF regional offices. The assessment tool (Module 3) was first field tested in Albania and Sultanate of Oman in September 2002. Starting in July 2003 with the Republic of Moldova self-assessment, a total of 28 assessments are conducted to-date. During this period, the primary vaccine store in Sultanate of Oman (2003 and 2004) and Republic of Moldova (2004) were found to achieve over 80% performance in all areas and were awarded with a recognition certificate by WHO and UNICEF. All feedback received from the meetings and assessments were incorporated in the package. A detailed history of changes can be found in the introduction section of the electronic version of Module 3 (the assessment tool) in the accompanying CD-ROM.

To support countries in training vaccine managers to perform the necessary skills and functions for their posts and to improve vaccine management practices that fully protect vaccines in countries starting from the arrival to the point of use, WHO initiated a training and follow up programme under the Global Training Network (GTN) in 2002. In 2003, a specialized training course on vaccine store management was developed based on EVSM Module 2 (Model quality plan) and the course is now offered by WHO accredited GTN/Vaccine Management training centres in Sultanate of Oman (Department of Communicable Disease Surveillance Control) and in South Africa (the Collaborative Centre for Cold Chain Management). The course accepts applicants from countries that conducted the EVSM assessment and adopt the initiative. To-date 46 participants have been trained in three different courses.

WHO would like to thank all those who contributed with their invaluable comments during the preparation of this package. WHO also thanks all countries that adopted the initiative and conducted assessments to pinpoint areas that require improvement.

Abbreviations

AD	auto-disable (syringe)
AEFI	adverse events following immunization
AMC	annual monthly consumption
°C	degrees centigrade
BCG	bacille Calmette-Guérin (tuberculosis vaccine)
cm	centimeters
CCM	cold chain monitor
DTP	diphtheria-tetanus-pertussis (vaccine)
DT	diptheria and tetanus toxoid (vaccine)
EEFO	earliest-expiry-first-out
ETA	expected time of arrival
EVSM	Effective Vaccine Store Management (initiative)
EPI	Expanded Programme on Immunization
g	grammes
H x W x L	height by width by length (or depth)
HepB	hepatitis B vaccine
Hib	*Haemophilus influenzae b* (vaccine)
hrs.	hours
kg	kilogrammes
lts or l	litres
ml	milliliters
mm	millimeters
m	meters
m^2	square meters
m^3	cubic meters
MMR	mumps-measles-rubella vaccine

MoU	memorandum of understanding
MR	measles-rubella vaccine
NGO	non-governmental organization
NRA	National Regulatory Authority
nbr.	number
OPV	oral polio vaccine
SLP	summary lot protocols
TT	tetanus toxoid (vaccine)
UN	United Nations
UNICEF	United Nations Childrens Fund
VVM	vaccine vial monitor
WHO	World Health Organization

Introduction

Vaccines are delicate products which are easily destroyed if handled incorrectly. The new vaccines, which are now being introduced, are also very expensive.

Experience shows that the national cold store remains the most critical element of an immunization system because this is where vaccines are received, stored and distributed in bulk. When there is an equipment or management failure at the primary level, large quantities of vaccine can be destroyed in a matter of a few hours. The immunization services of an entire country may thus be placed at risk and the financial loss can run to millions of dollars. This is no theoretical risk – it has happened. If the risk of such major and unacceptable failure is to be eliminated, then equipment must be procured, installed, operated and maintained to the highest international standards, and vaccines must be handled with the utmost attention to detail. Similarly high standards need to be maintained in the lower level stores, but effort and commitment at these lower levels may be wasted if the national store is inadequate.

The purpose of the **WHO-UNICEF Effective Vaccine Store Management (EVSM) initiative** is to encourage countries to procure and maintain equipment and to adopt management and training practices that fully protect vaccines in primary and intermediate vaccine stores. The initiative will provide countries with self-assessment tools, guidelines and model standards, focussed specifically on vaccine storage and distribution. Countries will use these tools and documents to assess weaknesses in equipment and operating procedures and to make the improvements necessary to meet the ten criteria set out in this document.

EVSM is based upon quality assurance principles. Vaccine quality can only be assured if the product is correctly stored and handled from point of manufacture to point of use. Managers and external assessors can only establish with certainty that quality has been maintained when detailed records are kept, and these records are reliable. If records are incomplete or inaccurate, the system cannot be properly assessed. Even if the vaccine *is* being stored and distributed correctly, a system that cannot be assessed is not "quality assured" and cannot be accepted as satisfactory under EVSM.

This package includes WHO-UNICEF joint statement on effective vaccine store management and four modules. Electronic versions of the documents, all reference materials and assessment tool in Excel are provided in the accompanying CD-ROM:

1) ***Module 1. Ten Global Criteria for Effective Vaccine Store Management:*** This short document describes the background to EVSM and sets out the ten key criteria against which cold store performance is to be evaluated.
2) ***Module 2. The Model Quality Plan:*** This document is a reference source. It takes the ten key criteria, breaks them down into sub-headings and supplements these sub-headings with supporting material.

3) ***Module 3. The Assessment Questionnaire:*** Initially the Assessment Questionnaire will be used by national inspectors to collect data in a standardized form so that it can be analysed in a consistent manner. Once this exercise has been carried out, and the national team is satisfied that the performance of the store is satisfactory, the national manager can request an international inspection based on the same questionnaire.

4) ***Module 4. Guidelines for Self-assessment:*** These guidelines are designed to help national managers to assess their own stores, using the Assessment Questionnaire. Once this exercise has been carried out, and the performance of the store is shown to be satisfactory, the national manager can request an international inspection.

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WHO-UNICEF Joint Statement on Effective Vaccine Store Management

WHO-UNICEF Effective Vaccine Store Management Initiative

WHO/IVB/04.16
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WHO-UNICEF joint statement on effective vaccine store management

Goal

Experience shows that critical management and equipment failures continue to occur in primary[1] and intermediate vaccine stores. Such failures, which may result in the destruction of large quantities of vaccine, can place the immunization services of an entire country at risk.

The goal of the **WHO-UNICEF Effective Vaccine Store Management (EVSM)** initiative is to encourage countries to procure and maintain equipment and to adopt management and training practices that fully protect vaccines in primary and intermediate vaccine stores. The highest priority lies at the primary vaccine store because this affects the quality of the vaccine delivered nation-wide.

Benefits

Effective management, adequate funding and well-maintained equipment are the keys to safe vaccine storage and delivery. The EVSM initiative is intended to set international standards for the management of vaccines in primary stores, to reinforce the importance of effective logistics, and to encourage countries to develop and maintain systematic and verifiable management practices and help secure adequate levels of funding.

Strategies

The EVSM initiative will provide countries with self-assessment tools, guidelines and model standards, focussed specifically on primary vaccine stores. Countries will use these tools and documents to assess weaknesses in equipment, training, operating procedures and funding arrangements and to make the improvements necessary to meet **ten global criteria** for effective vaccine store management.

If a country subsequently wishes to obtain independent assessment of its primary store, it will be able to request a formal inspection by an international team. This team may also assess the training of national assessors, whose duty would be to review the country's intermediate stores using tools, guidelines and model standards similar to those used for the primary store.

In order to satisfy the inspection criteria, there must be evidence that good practice is firmly established and that it has been maintained for a sustained period. Accordingly, both the self-assessment team and the international inspection team will examine records covering a continuous twelve month period. They will also evaluate procedures and equipment that are in place at the time of the inspection. Satisfactory performance is set as the vaccine store meeting at least 80% of each criterion.

[1] A primary vaccine store is a principal or main store that receives vaccine from the supplier.

The ten global criteria

Ten key criteria for effective vaccine store management were agreed at a meeting of experts, which took place at WHO Geneva in December 2001. These criteria form the policy foundation for the effective vaccine store management initiative and are listed below.

Over a period of twelve months:

1. Pre-shipment and arrival procedures have ensured that all shipments were in satisfactory condition when received in the primary stores.
2. All vaccines have been stored within WHO recommended temperature ranges.
3. The capacity of cold storage has been sufficient to meet the demand.
4. The buildings, equipment and transport available to the programme have enabled the cold store to function effectively.
5. All buildings, equipment and transport have been correctly maintained.
6. Stock management has been effective.
7. Deliveries of vaccine to the next level have been timely, sufficient and correct.
8. Minimal damage has occurred to the vaccine during distribution.
9. The facility has followed standard operating procedures.
10. Human and financial resources have been sufficient.

Each of these criteria is further broken down into a systematic set of sub-criteria, and these form a common skeleton upon which the EVSM initiative standards, guidelines and assessment tools are built.

Considering the above WHO and UNICEF strongly recommend that all countries adopt the EVSM initiative and conduct the necessary assessments and improvements leading to high quality management of their vaccine stores starting with the primary.

This policy statement is issued jointly by the World Health Organization, Geneva, Switzerland, and the United Nations Children's Fund (UNICEF Programme Division, New York, USA, and UNICEF Supply Division, Copenhagen, Denmark).

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Module 1

Ten global criteria for effective vaccine store management

WHO-UNICEF
Effective Vaccine Store
Management Initiative

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Contents

Introduction

"Ten global criteria for effective vaccine store management" is the first of four component modules that have been developed by the Effective Vaccine Store Management (EVSM) team, with the aim of helping countries to improve their vaccine storage and distribution systems. The four modules are as follows:

1. **Ten Global Criteria for Effective Vaccine Store Management:** This document describes the background to EVSM and sets out the ten key criteria against which cold store performance is to be evaluated.
2. **The Model Quality Plan:** This document is a reference source. It takes the ten key criteria, breaks them down into sub-headings and supplements these sub-headings with supporting material.
3. **The Assessment Questionnaire:** Initially the Assessment Questionnaire will be used by national inspectors to collect data in a standardized form so that it can be analysed in a consistent manner. Once this exercise has been carried out, and the national team is satisfied that the performance of the store is satisfactory, the national manager can request an international certification inspection based on the same questionnaire.
4. **Guidelines for Self-assessment:** These guidelines are designed to help national managers to assess their own stores, using the Assessment Questionnaire. Once this exercise has been carried out, and the performance of the store is shown to be satisfactory, the national manager can request an international inspection.

Ten global criteria for effective vaccine store management

Background to the initiative

Vaccines are delicate products which are easily destroyed if handled incorrectly. The new vaccines, which are now being introduced, are also very expensive.

Experience shows that the national cold store remains the most critical element of an immunization system because this is where vaccines are received, stored and distributed in bulk. When there is an equipment or management failure at the primary level, large quantities of vaccine can be destroyed in a matter of a few hours. The immunization services of an entire country may thus be placed at risk and the financial loss can run to millions of dollars. This is no theoretical risk – it has happened. If the risk of such major and unacceptable failure is to be eliminated, then equipment must be procured, installed, operated and maintained to the highest international standards, and vaccines must be handled with the utmost attention to detail. Similarly high standards need to be maintained in the lower level stores, but effort and commitment at these lower levels may be wasted if the national store is inadequate.

Programme staff and health workers are responsible for maintaining vaccine quality from the time when a shipment arrives in the country until the moment when a dose is administered – a period of at least 11 months. This is a substantial responsibility which should be placed in the hands of personnel who are adequately trained for the task.

The purpose of the **WHO-UNICEF Effective Vaccine Store Management initiative (EVSM)** is to encourage countries to procure and maintain equipment and to adopt management and training practices that fully protect vaccines in primary and intermediate vaccine stores. The initiative will provide countries with self-assessment tools, guidelines and model standards, focussed specifically on vaccine storage and distribution. Countries will use these tools and documents to assess weaknesses in equipment and operating procedures and to make the improvements necessary to meet the ten criteria set out in this document.

If a country wishes to obtain independent assessment, it will be able to request a formal inspection of its primary store(s). This inspection will be carried out by an international team after the country has already carried out its own internal self-assessment and has convinced itself that its equipment and procedures are satisfactory. The international inspection will include an assessment of the training of national inspection teams, whose duty will be to review the intermediate stores. The intention is that only the primary store(s) and the national training regime will be covered by the assessment process. The national inspection teams will inspect intermediate stores on a self-assessment basis.

The international team will verify that self-assessment of the primary store has been properly conducted and that management mechanisms are in place to ensure that good practice is observed, and is capable of being sustained. Typically, the team will assess storage and distribution, starting from the point where responsibility for the vaccines is formally handed over to the programme by the vaccine supplier. The assessment will end at the point where vaccine is handed over to the second (intermediate) level stores.

Similarly, the national assessment of intermediate stores will begin at the point of vaccine arrival in the store and will end at the point where vaccine is handed over either to a smaller intermediate store or to an immunization clinic. This procedure may be modified for very large countries.

Ten global criteria for effective vaccine store management

Ten key criteria for effective vaccine store management were agreed at a meeting of experts, which took place at WHO Geneva on 17th to 18th December 2001. These criteria form the policy foundation for the Effective Vaccine Store Management initiative.

The detailed implementation of the tools, guidelines and standards, which WHO/UNICEF will provide, will inevitably be subject to variation to suit national circumstances. Indeed, it will be a requirement of the process that countries have developed the model standards into a *Quality Plan* which suits local circumstances. However the ten key criteria are intended to have global applicability. They specify an agreed international standard of performance which all participating countries should aim to meet.

The following paragraph headings set out the criteria and briefly describe the reasoning behind each one. The self-assessment process is to be carried out over a twelve month period. If a storage facility already has access to comprehensive and reliable data, the self-assessment could be carried out retrospectively. Typically, however, the self-assessment process will begin once a programme has developed a country-specific Quality Plan, and the store has implemented the changes necessary to comply with the equipment and management standards set out in the plan. Satisfactory performance is set as the vaccine store meeting at least 80% of the each criterion.

The ten criteria are listed below.

1 Over a period of 12 months, pre-shipment and arrival procedures have ensured that all shipments were in satisfactory condition when received in the primary stores.

The arrival of vaccines in country, their temporary storage and clearance through customs and their subsequent transport to the central vaccine store is often the most critical stage in the cold chain. Unfortunately, experience shows that this is often the time when mistakes are made and delays occur. Such mistakes and delays may result in damage to the vaccine shipment.

The smooth arrival and handling of vaccine shipments depends on the manner in which each stage in the delivery process is performed. Many parties may be involved – for example the vaccine manufacturer, UNICEF Supply Division, the forwarding agent, the airline, the UNICEF field office, custom authorities, clearing agents and the ministry of health. Given the need to communicate accurate, time-sensitive information, and to act on this promptly, it is essential that strict guidelines are put in place to define the tasks involved, to assign responsibility for carrying out each task, and to monitor performance.

2 Over a period of 12 months, all vaccines have been stored within WHO-recommended temperature ranges.

All vaccines are sensitive biological substances. Over a period of time, they lose their potency – that is, their ability to give protection against disease. The higher the temperature to which the vaccine is exposed, the quicker is the loss of potency. Some vaccines are also sensitive to freezing, and this can cause irreversible damage.

In order to maintain their quality, all vaccines must be continuously stored at the appropriate temperature from the time they are manufactured until the moment when they are used. Once vaccine potency is lost, it cannot be regained or restored, and without proper care, any vaccine will eventually become ineffective. Once this occurs, the vaccine will no longer provide any protection against the target disease and the product is then useless. In some cases, loss of vaccine potency may also cause the vaccine to become more reactogenic.

The only way that it is possible to prove that vaccines have been stored at the correct temperature at all times is by using a continuous temperature recording device. This instrument should be regularly calibrated to ensure that it is accurate. Temperature records must be inspected regularly and retained for auditing purposes.

The recommended conditions for storing EPI vaccines are shown in the figure below. This diagram indicates the recommended storage temperatures and the maximum storage times at each level in the cold chain. At the higher levels of the cold chain, i.e., at primary, and regional intermediate stores oral polio vaccine (OPV) must be kept frozen between -15°C and -25°C). WHO no longer recommends that freeze-dried vaccines (measles, yellow fever, Hib and BCG) be shipped and stored at -20°C. Storing them at -20°C is not harmful but is unnecessary. Instead, these vaccines should be stored and transported at +2°C to +8°C. All other EPI vaccines should be stored at between +2°C and +8°C at all levels of the cold chain.

Diluents for vaccines are not sensitive to storage temperatures as the vaccines with which they are used. They are normally stored at ambient temperature, unless the diluent is packed with the vaccine. In this case they should be kept in the cold chain at between **+2°C to +8°C**. Diluent vials **must never be frozen.**

WHO recommended vaccine storage conditions

<table>
<tr><th></th><th>Primary</th><th colspan="2">Intermediate</th><th>Health</th><th>Health</th></tr>
<tr><th></th><th></th><th>Region</th><th>District</th><th>Centre</th><th>Post</th></tr>
<tr><td>OPV</td><td colspan="2">-15°C to -25°C</td><td rowspan="14" colspan="3">+2°C to +8°C</td></tr>
<tr><td>BCG</td><td colspan="2" rowspan="6">WHO no longer recommends that freeze-dried vaccines be stored at -20°C. Storing them at -20°C is not harmful but it is unnecessary. Instead, these vaccines should be kept in refrigeration and transported at +2° to +8°C.</td></tr>
<tr><td>Measles</td></tr>
<tr><td>MMR</td></tr>
<tr><td>MR</td></tr>
<tr><td>Yellow fever</td></tr>
<tr><td>Hib freeze-dried</td></tr>
<tr><td>HepB</td></tr>
<tr><td>DTP-HepB</td></tr>
<tr><td>DTP-Hib</td></tr>
<tr><td>Hib liquid</td></tr>
<tr><td>DTP</td></tr>
<tr><td>DT</td></tr>
<tr><td>TT</td></tr>
<tr><td>Td</td></tr>
<tr><td colspan="6">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.</td></tr>
</table>

3 Over a period of 12 months, the capacity of cold storage has been sufficient to meet the demand.

At all stores, but particularly at the primary level, new orders for vaccine must be placed early enough to ensure that a new shipment arrives before the safety stock level is reached. Supply intervals, working stock levels and safety stock levels should be selected to suit local circumstances, including available storage capacity and suppliers' lead times. Stores generally have longer supply intervals and larger safety stock levels the higher they are in the supply chain. For example, safety stock levels at the primary store are may be set at three month's normal consumption, whereas a health facility may only carry a two week safety stock.

When calculating the capacity of cold storage, programme managers must consider and balance a number of factors. These include financial considerations, vaccine expiry dates, supplementary immunization activities (national immunization days and campaigns), seasonal access, seasonal demand, and cold chain reliability.

Storage capacity should be enough to accommodate peak level stock requirements for the routine immunization schedule. In addition, satisfactory arrangements need to be made to ensure that vaccine supplied for national immunization days (NIDs) and campaigns can be temporarily accommodated in storage facilities that meet WHO standards.

4 Over a period of 12 months, the buildings, equipment and transport available to the programme have enabled the cold store to function effectively.

Vaccine stores should be housed in permanent buildings. These should be designed and constructed to a good standard to suit local climatic conditions. The building should have adequate spaces to accommodate the cold storage equipment: a store keeper's office; a temperature-controlled packing area; space for storing diluent, packaging materials and cold boxes, and space for freezing and storing icepacks. The store should have good access for vehicles and adequate telecommunications.

Wherever possible, refrigerators and freezers should be chosen from the WHO/UNICEF *Product Information Sheets*[1]. Similarly, wherever possible, cold rooms and freezer rooms should comply with current WHO specifications[2]. Adequate arrangements should be made to ensure continuous temperature monitoring and to ensure continuous refrigeration in the event of refrigeration equipment failure. Vaccine stores should have a reliable electricity supply, with an automatic standby power supply in the event of mains failure.

Reliable and suitable transport is essential for the delivery of vaccines and immunization supplies. Without access to an effective and reliable transport system, the operation of the cold store cannot be regarded as satisfactory.

5 Over a period of 12 months, all buildings, equipment and transport have been correctly maintained.

In order to prevent breakdowns affecting the performance of the immunization programme, all equipment, transport and buildings should be routinely maintained to a high standard using a programme of planned preventive maintenance. Emergency repairs should become the exception rather than the rule and there should be zero tolerance of breakdowns affecting key equipment.

In all cases there must be a reporting system which records breakdowns and the use and replacement of spare parts and which monitors the effectiveness of repair procedures.

6 Over a period of 12 months, stock management has been effective.

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

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

- Checking and recording details of vaccine consignments when they **arrive** at a storage point;
- Checking details and conditions of vaccine stocks **during** the time they are kept in storage;
- Checking and recording details of vaccines consignments when they **leave** the storage point for distribution to regions, provinces, districts and, eventually, the user.

In addition, good warehousing practices should be adopted and physical stock counts should be carried out on a regular basis to verify stock records.

[1] Unpublished document, reference code WHO/V&B/00.13
[2] Unpublished document, reference code WHO/V&B/02.33

7 Over a period of 12 months, deliveries of vaccine to the next level have been timely, sufficient and correct.

An effective vaccine distribution system should provide sufficient supplies of vaccine to lower level stores. Deliveries should be made in a planned and timely fashion. Every shipment should be accurately documented by means of a vaccine delivery report.

The earliest-expiry-first-out (EEFO) principle should generally be observed for deliveries. However, store keepers should be able to set aside the EEFO rule whenever vaccine vial monitor (VVM) status indicates heat exposure. Under such circumstances heat-exposed vaccines should be distributed first, regardless of expiry date.

A system should be adopted for managing short supplies.

8 Over a period of 12 months, minimal damage has occurred to the vaccine during distribution.

If correct practices are not followed during vaccine transport, vaccines may be damaged by exposure to excessive heat or to freezing temperatures. When vaccine is damaged in this way, this contributes to increased vaccine wastage and may result in short supplies.

New vaccines, such as hepatitis B freeze at close to 0°C. Recent evidence shows that vaccine freezing has now become the most serious consequence of poor distribution practice.

A monitoring and reporting system must be in place to ensure that vaccine damaged during transport is identified and replaced before it is distributed to the next level store. This can best be achieved by using electronic data loggers to record storage temperatures during transport. Data loggers should be used for all shipments from primary stores to the first level of intermediate stores, and elsewhere where possible.

9 Over a period of 12 months, the facility has followed standard operating procedures.

Standard operating procedures should be drawn up which are appropriate to each level in the distribution system. These procedures should be presented in a form which can be easily understood by the cadre of staff operating at each level.

Every cold store should be provided with a copy of these operating procedures, and staff should be trained to follow them and to keep appropriate records as evidence of compliance.

Standard procedures should cover the following topics:

- ordering/requisitioning vaccine;
- receiving a vaccine shipment:
- managing vaccine during storage, including temperature monitoring;
- distributing and transporting vaccines, including temperature monitoring.

10 Over a period of 12 months, human and financial resources have been sufficient.

An effective vaccine distribution system must be properly resourced. Staff must be adequately trained, and motivated to perform their duties. Sufficient recurrent funding must be made available to purchase vaccine and essential consumables such as fuel and spare parts, to pay and to train staff, and to maintain equipment. In addition capital resources or donor funding must be available to sustain a rolling renewal programme to prevent the accumulation of increasingly unreliable and obsolete equipment.

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Module 2

Model quality plan

WHO-UNICEF
Effective Vaccine Store Management Initiative

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Contents

Introduction

"Model Quality Plan" is the second of four component modules that have been developed by the Effective Vaccine Store Management (EVSM) team, with the aim of helping countries to improve their vaccine storage and distribution systems. The four modules are as follows:

1. **Ten Global Criteria for Effective Vaccine Store Management:** This document describes the background to EVSM and sets out the ten key criteria against which cold store performance is to be evaluated.
2. **The Model Quality Plan:** This document is a reference source. It takes the ten key criteria, breaks them down into sub-headings and supplements these sub-headings with supporting material.
3. **The Assessment Questionnaire:** Initially the Assessment Questionnaire will be used by national inspectors to collect data in a standardized form so that it can be analysed in a consistent manner. Once this exercise has been carried out, and the national team is satisfied that the performance of the store is satisfactory, the national manager can request an international certification inspection based on the same questionnaire.
4. **Guidelines for Self-assessment:** These guidelines are designed to help national managers to assess their own stores, using the Assessment Questionnaire. Once this exercise has been carried out, and the performance of the store is shown to be satisfactory, the national manager can request an international inspection.

1. Pre-shipment and arrival procedures

1.1 The requirements set out in the vaccine arrival report have been complied with for all shipments.

Responsible staff for this sub-section: EPI manager and storekeepers.

Reference documents for this sub-section:

- *Ensuring quality of vaccines at country level – A guideline for health staff* (WHO/V&B/02.16).
- *Guidelines on the international packaging and shipping of vaccines* (WHO/V&B/01.05).
- *Temperature monitors for vaccines and the cold chain* (WHO/V&B/99.15).
- *Quality of the cold chain: WHO–UNICEF policy statement on the use of vaccine vial monitors in immunization services,* WHO/V&B, 1999 (WHO/V&B/99.18).

1.1.1 Use the standard UNICEF Vaccine Arrival Report (VAR) form wherever possible.

Knowledge and responsibilities: The person responsible for checking the shipment should know how to read VVMs, to cold chain monitors (CCMs) and freeze indicators.

The integrity of vaccines on arrival in the country of destination should be checked by verifying that the cold chain has been properly maintained throughout the period of transport as confirmed by the temperature-monitoring devices contained in the shipment. This check is most conveniently recorded on a standard Vaccine Arrival Report (VAR).

Figure 1.1.1. A shows the standard VAR form. If local arrival procedures differ significantly, the standard VAR form may be used as a basis for a revised form. However the revised form should include all the principal procedures indicated on the standard form.

Figure 1.1.1.A – Standard Vaccine Arrival Form

This report is to be filled in by authorized staff, ratified by the Store Manager or the EPI Manager, and forwarded to UNICEF ***within 3 days*** of vaccine arrival. Use one report for each vaccine in the shipment.

COUNTRY	
REPORT No.	

Date of report	

Place, Date and Time of Inspection	Name of Cold Store, Date and Time vaccines entered into cold store

PART I-ADVANCE NOTICE

MAIN DOCUMENTS	Date received by consignee	Copy Airway Bill (AWB)	Copy of Packing List	Copy of Invoice	Copy of Release Certificate
Pre-advice					
Shipping notification		Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

List other documents (if requested)	

PART II- FLIGHT ARRIVAL DETAILS

AWB Number	Airport of Destination	Flight No	ETA as per notification		Actual time of arrival	
			Date	Time	Date	Time

NAME OF CLEARING AGENT: _____ ON BEHALF OF: _____

PART III- DETAILS OF VACCINE SHIPMENT

Purchase Order No.	Consignee	Vaccine Description (Type and doses/vial)	Manufacturer	Country

Vaccine				Diluent/droppers			
Lot Number	Number of Boxes	Number of Vials	Expiry Date	Lot Number	Number of Boxes	Number of Units	Expiry Date

(Continue on separate sheet if necessary)

	Yes	No	Comments
Was quantity received as per shipping notification?	☐	☐	
If not, were details of short-shipment provided prior to vaccine arrival?	☐	☐	

Report No.	

PART IV-DOCUMENTS ACCOMPANYING THE SHIPMENT

Invoice	Packing List	Release Certificate	Vaccine Arrival Report	Other
Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	
Comments				

PART V- STATUS OF SHIPPING INDICATORS

Total number of boxes inspected				
Coolant type:	Dry ice ☐	Icepacks ☐	No coolant ☐	
Temperature Monitors present:	VVM ☐	Cold Chain Card ☐	Freeze Watch ☐	Recorder ☐

PROVIDE BELOW DETAILS OF STATUS ONLY WHEN PROBLEMS ARE OBSERVED:

Box Number	LOT NO	VVM				Cold Chain Monitor				Freeze Watch Burst?		Date/time of inspection
		1	2	3	4	A	B	C	D	Yes	No	
		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

(Continue on separate sheet if necessary)

TEMPERATURE RECORDER (if applicable, send clear copy of chart together with this report)	Box No.	Model	Serial No.

PART VI- GENERAL CONDITIONS OF SHIPMENT

What was the condition of boxes on arrival?	
Were necessary labels attached to shipping boxes?	
Other comments: (continued in separate sheet if necessary)	

PART VII- NAME AND SIGNATURE

Authorized Inspection Supervisor	DATE	Central Store or EPI Manager	DATE

For UNICEF Country Office use only

Date received by Country Office: _____ ; **Contact Person:** _____

Guidelines for completing the Vaccine Arrival Report (VAR)

The purpose of the Vaccine Arrival Report is to monitor cold chain conditions during transport, compliance/deviations with shipping instructions and ensure adequate record keeping of information related to vaccines. It can also serve as the basis for documenting claims or initiating corrective action if problems occur.

Recipient Governments, UNICEF Country Offices and UNICEF Supply Division are responsible for the implementation of the Vaccine Arrival Report, and for taking corrective action as necessary.

Components of the report:

Use one form for each shipment and for each vaccine in the shipment (in shipments of DTP-HepB+Hib vaccine, one form should be used for DTP-HepB and a separate one for Hib). **In the case of short-shipments (part of the original quantities not delivered), one report should be completed for each part of the delivery.**

The heading of the report is for the name of recipient country, report number and details of place and date of inspection and storage.The report number is an internal number for organizing records, with the format COUNTRY CODE-YEAR-REPORT NUMBER (e.g. BUR-2002-001). In the case of short-shipments, the numbers for the different deliveries (for one vaccine type only) would be BUR-2002-001.1, BUR-2002-001.2 etc.

Part I- ADVANCE NOTICE: Indicate dates and details of documents received in advance of the vaccine shipment.

Part II- FLIGHT ARRIVAL DETAILS: Fill in details of expected and actual arrival times for the shipment, as well as name of clearing agent and for whom they act (i.e. MoH/UNICEF, etc).

Part III- DETAILS OF VACCINE SHIPMENT: Fill in details of the order (purchase order number, consignee, vaccine description etc). For **each batch of vaccine** included in the shipment, indicate the number of **shipping boxes, vials and expiry date**. The same applies to diluent/droppers when present. This information is included in the packing list. **Diluents for freeze-dried vaccine and droppers for OPV should be considered as integral parts of the vaccine, and always reported on the same form. Separate delivery of diluent/droppers should be considered as short-shipments.** The figures entered in the number of boxes' column should always match the number shown in the packing list. If it does not, indicate if advance notice of a change in the quantity was provided.

Counting of the number of individual vaccine packs in each shipping box is not required in the report.

Part IV- DOCUMENTS ACCOMPANYING THE SHIPMENT: The box containing the shipment documents should be indicated in the packing list (often these will be in box number 1). Verify that all necessary documents are present and complete the form accordingly. If the box is not identified in the packing list or the documents made available through other means (courier, pouch), please indicate it in the section reserved for comments.

PART V- STATUS OF SHIPPING INDICATORS: Inspection of the temperature indicators is an essential part of the report. The temperature monitors should be checked **in all boxes** before vaccines are put into cold storage. In the case of very large shipments, or when immediate storage in the shipping boxes is required, a representative number of boxes should be checked prior to placing the shipment in the cold store. Complete inspection of all boxes the next day, or as soon as possible thereafter, indicating date and time when the complete inspection took place.

Indicate the number of boxes inspected (this should equal the total number in the shipment), the type of coolant used and details of any temperature exposure if detected. **Only boxes in which the temperature monitors show a change of color that indicates potential damage to vaccines (VVM stage 3 and 4, cold chain monitor card as per vaccine/threshold table in card, freeze watch burst) should be reported on this report.**

Vaccines in boxes in which indicators show exposure to temperatures that risk damage to the vaccine should be identified clearly in the cold room for further assessment of their condition. **DO NOT DISCARD VACCINES UNTIL ASSESMENT IS COMPLETED.**

If temperature recorders are included, indicate the box(es) in which the recorder was shipped, the model and the serial number(s). Please attach a clear photocopy of the chart to the VAR.

PART VI- GENERAL CONDITIONS OF SHIPMENT: Indicate if the shipping boxes were received in good condition, if all the necessary labels on the outside of the shipping boxes were present and add any comments.

PART VII- NAME AND SIGNATURE: The form should be signed by the authorized person responsible for the inspection and by the Central Store Manager or the EPI Manager. Once completed, the report should be sent to the UNICEF Country Office, to be forwarded to UNICEF Supply Division (Immunization Team **Fax: +45 35269421**, email mcaron@unicef.org, and ccooper@unicef.org**)**.

Any problems reported will be taken to the appropriate levels (i.e. manufacturer, forwarder, WHO, etc) for necessary action and correction.

For every vaccine received, complete the form in accordance with the guidelines shown on the reverse of the VAR. Check that all paperwork was received on time and has been correctly completed, check the condition of boxes, and check for short-shipments and short expiry dates. Also check the status of VVMs, CCM cards and freeze indicators. Where shipments arrive with electronic temperature data loggers, the person responsible should follow the instructions supplied with the data logger. Record the data and attach the record to the VAR. If no instructions are provided and the person responsible does not know how to use the data logger, the device should be returned to the vaccine supplier. Request that adequate instructions are supplied with all future shipments.

Finally, have the VAR signed and counter-signed and circulate copies as indicated on the form (refer also to sub-section 1.4). Do not accept any box of vaccine unless it has arrived in good condition.

Record keeping: Retain completed VAR forms, Pre-advice, Shipping notification, Airway Bill, Packing List, Invoice and Release Certificates for a minimum period of three years.

1.1.2 Take immediate action if a shipment arrives in the primary store in unsatisfactory condition, or if vaccine arrival procedures have not been followed correctly.

Knowledge and responsibilities: The person responsible for checking the shipment should understand shipping procedures. The VAR provides the means for recording and reporting damage to vaccine, as well as procedural inadequacies in the shipping process. In conjunction with other supporting data, the VAR is used as the basis for documenting claims or demands for corrective action.

"Immediate action" means that the vaccine manufacturer, freight forwarder and other relevant organizations should be faxed a copy of the VAR as soon as it has been completed. The VAR should be accompanied by a letter requesting replacement of the damaged vaccine. See Part VII of the *Guideline for filling vaccine arrival report* on the back of the VAR form. Follow this up with a formal claim for replacement, accompanied by relevant supporting evidence – for example, photographs.

For countries receiving vaccines from UN agencies, all complaints should be sent immediately the procurement agency's local country office, which will follow the matter up with the agency's procurement organization. Depending on the nature of the complaint, the procurement organization may handle the issue by itself or may request assistance from WHO.

For countries procuring vaccine directly, all complaints should be handled bilaterally with the vaccine manufacturer. Countries are also entitled to request WHO assistance should this be needed.

Figure 1.1.2.A sets out the vaccine arrival and complaints procedures for UNICEF procured vaccines. These procedures may be adapted for other procurement routes.

Figure 1.1.2.A - Procedure for reporting vaccine arrivals

Arrival of vaccines and customs clearance.

↓

Inspection at airport or central cold stores. Vaccine Arrival Report (VAR) filled in and signed.

↓

Copy of VAR sent to UNICEF Country Office.

↓

Copy of VAR sent to UNICEF Supply Division, Copenhagen (SD)

↓

INDICATOR	OK	DEFECTIVE
Advance notification	Recorded	SD to follow-up with forwarder
Vaccine type/expiry	Recorded	SD to follow-up with manufacturer Eventual report to WHO/V&B for further investigation if necessary
Shipping documents	Recorded	SD to follow-up with forwarder or manufacturer Eventual report to WHO/V&B of problems related to release certificate
Quantities received	Recorded	SD to follow-up with forwarder/manufacturer
Status of temperature indicators	Recorded	SD to report to WHO/V&B, investigation to be carried out

Any defect in the process can lead to compensation claims and/or rejection of a shipment. Each individual situation will be investigated and dealt with by all involved parties.

If the quantity of damaged vaccine is substantial, this could affect immunization delivery. In such cases, emergency measures will have to be taken to obtain sufficient vaccine to maintain the programme.

Record keeping: Retain VARs and all correspondence relating to unsatisfactory shipments or procedures for a minimum period of three years.

1.2 Lot release certificates for all shipments are in the possession of the NRA and/or the EPI manager.

Responsible staff for this sub-section: National Regulatory Authority (NRA) and/or EPI manager.

Reference documents for this sub-section:

- *Ensuring quality of vaccines at country level – A guideline for health staff* (WHO/V&B/02.16).

1.2.1 All vaccine shipments are to be accompanied by a lot release certificate (one per lot) issued by the NRA of the country of origin.

Knowledge and responsibilities: Responsible staff must ensure that all vaccines, including those received from UN sources, are licensed for use in their country. They should also ensure that all adverse events following immunization (AEFI) are monitored by an effective field performance surveillance system.

In countries where the National Regulatory Authority (NRA) is not fully functional[2], a simplified and abbreviated vaccine registration procedure may be adopted in cases where vaccines are supplied from UN sources. This simplified procedure exempts the NRA in the importing country from carrying out a detailed protocol review on incoming vaccine lots. The reason for this relaxation is that UN-supplied vaccines are of assured quality. This is because lot release requirements are imposed by the NRA in the country of manufacture. In addition, WHO evaluates both the NRA and the manufacturer and also carries out regular re-assessments of these bodies. If the receiving country has no NRA, or does not have the skills necessary to perform a protocol review, vaccines may then be released.

In countries with a fully functional National Regulatory Authority (NRA) a detailed protocol review process should also be carried out for each lot, including checks on the lot release certificates supplied by the country of origin, checks on transport and storage conditions,[3] and checks on the manufacturing summary of production and control.[4]

In all cases the lot release certificate from the NRA of the country of origin should be a condition for acceptance of the vaccine and for its subsequent distribution. Note that the manufacturer's own internal lot release *cannot* be considered as equivalent to the NRA lot release certificate for the purpose of releasing vaccines.

[2] "Fully functional" in this context means that there should be an independent system implementing the two separate functions of licensing and field surveillance (AEFI).
[3] The VAR should record transport and storage conditions – see sub-section 1.1 above.
[4] Using the WHO summary protocol, or similar national criteria.

Remember, the manufacturers' release documents – and any other papers which may accompany a shipment – ***do not replace*** and are ***not a substitute*** for the lot release certificates issued by the National Regulatory Authority of the country of origin.

Record keeping: Keep lot release certificates from the NRA of the country of origin. Keep summary lot protocols (if supplied). Retain these records for a minimum period of five years.

1.2.2 The NRA in the receiving country should undertake lot release procedures for all vaccines that are obtained from non-UN sources, including all vaccines produced and used within the receiving country.

Knowledge and responsibilities: A mandatory lot release procedure should be in place in any country which procures vaccines from sources other than the UN agencies, as well as in countries which produce their own vaccines.

This lot release procedure must include a thorough check of the release certificate supplied by the NRA of the country of origin, a review of the lot summary protocols, and a review of all other supporting documentation supplied by the manufacturer. These supporting documents are submitted by the manufacturers upon request and provide summary data on the history of each of the vaccine lots included in the shipment, together with technical information on the production steps, quality control tests and results obtained. In some cases, manufacturers will send summary lot protocols (SLPs) for the vaccine together with the shipping documents, whether or not the country has requested them.

A receiving country which is procuring vaccine from non-UN sources may not have the expertise within its own NRA to review the summary protocols. In such circumstances, and in order to avoid delays in the distribution of the vaccine, outside expertise should be obtained from another NRA or National Control Laboratory. However, the final decision to release the vaccine still remains with the NRA in the receiving country.

Record keeping: Keep lot release certificates from the NRA of the country of origin. Keep summary protocols (if supplied). Retain this documentation for a minimum period of five years.

1.3 Reliable arrangements have been agreed with the relevant authorities to clear vaccines through customs. This arrangement is to apply to vaccine arrivals on weekdays, weekends and holidays.

Responsible staff for this sub-section: EPI manager and staff responsible for procuring and clearing vaccine.

Reference documents for this sub-section:

- *Ensuring quality of vaccines at country level – A guideline for health staff* (WHO/V&B/02.16).

1.3.1 Establish effective working arrangements with the customs authorities and with the NRA.

Knowledge and responsibilities: All responsible staff should understand customs clearance procedures and should know whom to contact when a vaccine delivery is expected.

The arrival of vaccines in country, their subsequent clearance through customs and their transport to the central vaccine store are the most critical stages in a vaccine shipment. Unfortunately, experience shows that this is often the time when mistakes are made and delays occur. Damage to the shipment is often the result.

The smooth arrival and handling of vaccine shipments depends on the manner in which each element in the delivery process is performed. Given the number of parties involved, (for example the UNICEF Supply Division, the manufacturer, the forwarder, the airline, the UNICEF field office, custom authorities, clearing agents, the EPI Unit, etc.), and the need to communicate accurate, time-sensitive information, it is essential that strict guidelines are in place to determine and assign responsibilities for every step of the process. These responsibilities are described in the terms and conditions of the tender documents, and are further detailed in the individual contracts, with specific conditions depending on the country of destination.

Responsible staff should discuss and agree standard clearance and contingency arrangements with the customs authorities. Establish that customs staff are adequately trained to handle vaccines and similar temperature-sensitive products. Ensure that arrangements will be followed whenever the vaccine arrives – including weekends and holidays. If it is possible to do so, a written Memorandum of Understanding (MoU) should be drawn up between the parties.

The MoU should also establish contingency arrangements in the event of cold room, air-conditioning or heating failure. These procedures should be reviewed whenever problems arise and, in all cases, at least once a year.

The risk of vaccine being mishandled is significantly reduced if the customs authorities will allow the shipment to be taken directly to the primary store before it has been formally cleared. Under this arrangement the vaccine is temporarily held "in bond" at the primary store, and cannot be used until a customs officer has visited the store to clear the shipment. If there is any doubt about the quality of the cold storage facilities at the port of entry, this option should be negotiated as part of the MoU.

Record keeping: Records of meetings with the customs authorities, Memorandum of Understanding, reporting procedures in the event of delays and other problems with customs clearance.

1.4 Satisfactory procedures/facilities exist for ensuring the integrity of vaccine during clearance.

Responsible staff for this sub-section: Immunization staff responsible for clearing vaccine and the responsible customs staff.

Reference documents for this sub-section:

- *Guidelines on the international packaging and shipping of vaccines* (WHO/V&B/01.05).

1.4.1 Ensure vaccine is cleared through customs without exposing it to adverse temperatures.

Knowledge and responsibilities: Responsible customs staff should understand the standard operating procedures set out in the Memorandum of Understanding described in para. 1.3.1. Responsible immunization staff should periodically inspect and approve the holding store, as described in para. 1.4.2. The reference document requires all vaccines to be stored in a cold room at +2°C to +8°C pending reshipment or collection. However, if vaccines are reliably cleared through customs within 24 hours of arrival, temporary storage inside a transit warehouse should be acceptable. The temperature in the storage space must not drop below +2°C or rise above +35°C. In hot climates an air-conditioned room is desirable. In cold climates a heated room may be necessary.

In situations where vaccine cannot be cleared within 24 hours, the shipment should be taken directly from the aircraft to a +2°C to +8°C cold room, where it should be kept until collection.

Record keeping: Memorandum of Understanding; standard inspection checklist, as described under para. 1.4.2.

Materials and equipment: As described under para. 1.4.2.

1.4.2 Ensure that the equipment and monitoring procedures in the holding store are satisfactory.

Knowledge and responsibilities: *Immunization staff* responsible for inspecting the holding facilities should check that:

- customs staff who are responsible for holding vaccines are adequately trained to look after it and know what to do if there is an equipment failure;
- the cold room is large enough to accommodate the largest anticipated vaccine shipment;
- the cold room is fitted with a continuous temperature recording device and that it is capable of maintaining the required temperature range (+2 °C to +8 °C);
- the cold room has duplicate (standby) refrigeration units (this is desirable, but not essential);
- the cold room is fitted with a secure lock.

Customs staff responsible for looking after vaccines in the holding store should:

- monitor and record the temperature of the holding room or cold room at least twice in 24 hours, 7 days per week, following the procedures set out in para. 2.1.3;
- maintain the cold room temperature between +2 °C to +8 °C;
- store vaccine in the cold room at least 200mm off the floor and away from the danger zone close to the evaporator (see para. 4.3.1);
- restrict access to the holding store to authorized personnel only.

Record keeping: Memorandum of understanding; temperature records.

Materials and equipment: +2°C to +8°C cold room and temperature monitoring equipment.

1.5 Satisfactory arrangements are in place for transporting vaccine to primary storage, including arrangements for the maintenance of correct temperatures during transport.

Responsible staff for this sub-section: Immunization staff responsible for clearing vaccine, staff responsible for transport operations and drivers.

Reference documents for this sub-section:

- *SCF Transport Management Handbooks,* Save the Children Fund, 1995.
  No. 1: An introduction to the role of field management in the provision and operation of transport
  No. 2: Managing your fleet
  No. 3: Fleet composition and size: replacing or adding vehicles to the fleet
  No. 4: Competence and testing of drivers
  No. 5: Driver's responsibilities

1.5.1 Ensure that reliable transport is available to move vaccine from the holding store to the primary store.

Knowledge and responsibilities: Responsible staff should be trained in transport management.

Where vehicles are owned and operated by others, make sure that they are reliable and well maintained.

Where vehicles are owned and managed by the immunization programme, carry out planned preventive maintenance on all vehicles in accordance with the recommendations of the vehicle manufacturer. Maintain vehicle logbooks and service records. If an effective transport management system is not in place, then one should be established.

Record keeping: Training records, vehicle logbooks and vehicle service records.

Materials and equipment: Vehicles and spare parts.

1.5.2 In hot climates do not expose shipping containers to excessive temperatures during transport. In cold climates, do not expose shipping containers to temperatures below 0°C during the journey. If necessary, use warm packs to protect freeze-sensitive vaccines.

Knowledge and responsibilities: Teach immunization staff and drivers the importance of transporting vaccines at acceptable temperatures. In cold climates, demonstrate the use of warm packs. Teach drivers how to protect the vaccine in the event of an emergency – for example after a breakdown or an accident. Always transport vaccine in a covered vehicle to protect it against sun and weather and to keep it secure.

In *hot climates* make sure that the interior of the vehicle is as cool as possible before the journey starts. Always park the vehicle in the shade and keep the goods compartment well ventilated in order to reduce heat build-up. The vaccine will already have had a long air journey, and will have spent time being cleared through customs. As a result, the original coolant in OPV shipments will most likely have melted. In the case of other vaccines the water packs inside the shipping containers will have heated up. For this reason it is good practice to keep shipping containers in a cold room at +2°C to +8°C whilst they are awaiting customs clearance – see para. 1.4.1. If this is done, the vaccine will start its onward journey at a safe temperature.

In *cold climates* there is a risk that freeze-sensitive vaccine and diluents may be damaged during transport. Separately packed diluents are particularly vulnerable as they are not shipped in insulated containers. If the goods compartment cannot be kept above 0°C throughout the journey then it is essential to use "warm packs" to protect the vulnerable vaccines. The box below sets out the procedure which should be followed.

Figure 1.5.4.A - Procedure for using 'warm packs'

"Warm life" is defined as the number of hours that a vaccine carrier or cold box can maintain vaccine temperatures above 0°C or before ice packs are frozen.

Health care workers can use the same vaccine carriers or cold boxes currently found in use, including ice packs that are above 10°C and below 24°C, to safely transport vaccines in extremely cold environments without freezing them. However, caution should be taken because not all vaccine carriers or cold boxes will have a good "warm life" due to poor construction and low quality material. Using containers constructed with polyurethane insulation will provide the best protection for transporting vaccines and will guard them from freezing or from reaching internal temperatures above 10°C for a longer period of time.

The "warm life" performance for whatever type of insulated container is selected for the transportation of vaccines can be determined by simply following this procedure: use empty vaccine vials and load the container with non-frozen ice packs designed for it and place it outside in the cold air and monitor the amount of time required to completely freeze the packs. These data will provide all workers with a parameter for monitoring shipments in extremely cold environments. Ice packs can be stored either in a refrigerator or on a shelf in the same room where the vaccine load will be taken from the refrigerator and put into a container. The temperature of the room where the ice packs are stored should be below 24°C. The staff (including drivers) involved in the handling and transportation of vaccines in extremely cold environments must be alerted to change frozen ice packs with non-frozen ones.

In very cold environments, ice packs stabilized at an ambient temperature of ±24°C can be used for the transportation of these vaccines for a period not exceeding 8 hours. The vaccines are very heat stable and the short time (< 8 hours) that they are subjected to temperatures between 10°C to 24°C will not harm them.

Source: P Carrasco, PAHO/WHO, Washington, DC; C Herrera, D Rancruel, M Rosillo, Universidad del Valle, Cali, Colombia, "Protecting vaccines from freezing in extremely cold environments", Canada Communicable Disease Report 21:11, 1995:95–101.

If there is an *emergency* during the journey, the driver must know what actions to take in order to protect the vaccine. He/she should have a list of available temporary storage points along the route – for example, a list of hospitals. The actions to be taken are very dependent upon the local infrastructure, but the following illustrates an example:

1) If possible, arrange for the vehicle to be moved to a place where it is secure and is protected against excessive heat or cold. If the vehicle is immobile, make sure that it is locked and/or well guarded.
2) Get in touch with the nearest available temporary storage point and make arrangements for the vaccine to be collected.
3) Contact relevant headquarters, inform the duty officer of the emergency and arrange for a replacement vehicle and driver to be sent to the chosen temporary storage point.
4) Accompany the vaccine and ensure that it is stored under safe conditions.
5) Return to the vehicle to arrange for repairs or recovery.

Record keeping: Training records.

Materials and equipment: Warm packs, etc. in cold climates.

1.6 Where a clearing agent is used, the facilities and performance of the agent have been adequately monitored.

Responsible staff for this sub-section: EPI manager or other staff member responsible for contracting-out services.

Reference documents for this sub-section:

- *Managing drug supply, 2nd ed.* Kumarian Press, 1997. Chapter 22: *Importation and port-clearing.*

1.6.1 Draw up a written contract with the clearing agent.

Knowledge and responsibilities:[5] The responsible staff member should understand customs clearance procedures and should be able to define precisely the services expected of a clearing agent.

Establish a contract with the clearing agent on the basis of tenders invited from several pre-qualified companies. It is the agent's duty to understand local rules and practices and to handle all the relevant import and customs clearance documentation. The agent must be made fully responsible for ensuring that the vaccine is cleared and delivered to the primary store within an agreed maximum period.

Tenderers should be asked to specify all charges and rates and should clearly identify the duties that they will perform. Before an agent is appointed, obtain satisfactory business references and inspect the agent's facilities to ensure that good business and materials handling practices are observed and that the agent is equipped to handle and to store vaccines. There should be an adequate contract review procedure with a termination clause and penalties in the event of performance failure.

Record keeping: Contract with the clearing agent. Maintain records of all correspondence with the agent as required under government standing orders.

1.6.2 Monitor the performance and facilities of the clearing agent and monitor his temperature records.

Knowledge and responsibilities: All responsible staff should have a general understanding of customs clearance procedures and should know whom to contact at the clearing agent.

The EPI manager, or a delegated member of staff, should monitor the performance of the clearing agent according to the norms and standards indicated in sub-sections 1.1 to 1.5 above, to the extent that these are relevant to the performance of the clearing agent's duties, as defined in his contract. Refer also to para. 1.4.2 for a cold room inspection checklist.

Record keeping: Contract with the clearing agent, and as listed in sub-section 1.1 to 1.5 above. Checklist.

[5] This paragraph is adapted from *Managing drug supply, 2nd ed.* Kumarian Press, 1997. Chapter 22: *Importation and port-clearing.*

2. Maintain correct storage temperatures

One of the fundamental aims of the Effective Vaccine Store Management initiative is assist countries to eliminate vaccine losses arising from incorrect storage conditions. A well managed store should be able to achieve this. However, it is accepted that there may be some wastage as a result of unforeseen circumstances. Accordingly a target has been set against which programmes will be evaluated. This target is as follows:

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

2.1 Continuous temperature records are available, and these records demonstrate that vaccine has been stored correctly in both permanent and temporary cold stores.

Responsible staff for this sub-section: EPI manager, storekeepers and all staff members who handle vaccines, duty staff members responsible for monitoring storage temperatures, a senior staff member who has been trained to review temperature records.

Reference documents for this sub-section:

- *Ensuring quality of vaccines at country level – A guideline for health staff* (WHO/V&B/02.16).
- Logistics and cold chain for primary health care series:
  Module15: User's handbook for compression refrigerators. Note: Although it contains useful information, the current version of this document is out of date. It should be used with caution.
- *User's handbook for vaccine cold rooms or freezer rooms* (WHO/V&B/02.31).
- *Looking after a cold room or freezer room: self-assessment tool* (WHO/V&B/02.30).
- *Quality of the cold chain: WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services* (W HO/V&B/99.18).
- *Getting started with vaccine vial monitors: Questions and answers on field operations* (WHO V&B/02.35).

2.1.1 Store all vaccines and diluents at the correct temperature.

Knowledge and responsibilities: Responsible staff must know the correct storage temperature for every vaccine, diluent and vaccine/diluent combination. Figure 2.1.1.A shows the current WHO recommendations. A version of this table should be prominently displayed in the vaccine store. If any other vaccines or pharmaceuticals are kept in the cold store, these should be added to the table. Staff should also know the temperatures at which the various adsorbed vaccines freeze and should know that freezing damages these vaccines.

Figure 2.1.1.A - WHO recommended vaccine storage conditions

<table>
<tr><th rowspan="2"></th><th rowspan="2">Primary</th><th colspan="2">Intermediate</th><th rowspan="2">Health Centre</th><th rowspan="2">Health Post</th></tr>
<tr><th>Region</th><th>District</th></tr>
<tr><th></th><th>6 months[a]</th><th>3 months</th><th>1 month</th><th>1 month</th><th>Daily use</th></tr>
<tr><td>OPV</td><td colspan="2">-15°C to -25°C</td><td colspan="3" rowspan="14">+2°C to +8°C</td></tr>
<tr><td>BCG</td><td colspan="2" rowspan="6">WHO no longer recommends that freeze-dried vaccines be stored at -20°C. Storing them at -20°C is not harmful but it is unnecessary. Instead, these vaccines should be kept in refrigeration and transported at +2° to +8°C.</td></tr>
<tr><td>Measles</td></tr>
<tr><td>MMR</td></tr>
<tr><td>MR</td></tr>
<tr><td>Yellow fever</td></tr>
<tr><td>Hib freeze-dried</td></tr>
<tr><td>HepB</td></tr>
<tr><td>DTP-HepB</td></tr>
<tr><td>DTP-Hib</td></tr>
<tr><td>Hib liquid</td></tr>
<tr><td>DTP</td></tr>
<tr><td>DT</td></tr>
<tr><td>TT</td></tr>
<tr><td>Td</td></tr>
<tr><td colspan="6">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.</td></tr>
</table>

All vaccines, diluents and vaccine/diluent combinations must be stored at the temperature recommended in Figure 2.1.1.A. If there is any doubt about the correct temperature for a particular vaccine, it must be stored in a cold room, and not in a freezer room or vaccine freezer. Do this, for example, if you are uncertain whether a freeze dried vaccine has been packed with its diluent. Diluent must *never* be frozen.

Record keeping: Maintain training records to show which staff members have received training in vaccine handling.

Materials and equipment: Storage temperature charts.

2.1.2 Use stock records to demonstrate that all vaccines and diluents have been stored in accordance with current WHO storage temperature recommendations.

Knowledge and responsibilities: Responsible staff should understand the correct storage temperatures as described in para. 2.1.1, and should have a working knowledge of the stock management system. Each time vaccine is received in the store, check the correct storage temperature for the vaccine or vaccine/diluent combination. Use the stock management system to record the temperature at which it has been stored.

Record keeping: Figure 2.1.2. A shows an example of a stock record form. When the vaccine is received in the store, use the "Remarks" to record the storage temperature used.

Figure 2.1.2.A - Example of a stock record form for vaccine or diluent

Store Name: _____

Product Name: _____ **Description:** _____ **Most recent AMC:** _____ **AMC Cal. date** __ / ___ / __

		Quantities						
Date	Voucher No	Opening Balance (doses)	Received (doses)	Issued (doses)	Loss/ Adjustments (doses)	Balance (doses)	Stock Level (months)	Remarks/Initials
A	B	C	D	F	G	H	I	J
/ /								
/ /								
/ /								
/ /								
/ /								
/ /								
/ /								
/ /								
/ /								
/ /								

AMC: Annual monthly consumption.

Materials and equipment: Stock record forms, etc.

2.1.3 Inspect temperature records at least twice every 24 hours, 7 days per week. Maintain a contingency plan.

Knowledge and responsibilities: Responsible staff should know that the safe operating temperature for cold rooms and vaccine refrigerators is between +2°C to +8°C and that the safe operating temperature for freezer rooms and vaccine freezers is between -15°C to -25°C. They should know how to read a dial thermometer or digital thermometer accurately, (avoiding parallax reading errors and decimal point reading errors for example), and they should also know how to read the temperature trace on a chart recorder, electronic recorder, or other continuous recording device.

Responsible staff should know how to complete a temperature inspection record sheet similar to the one shown in Figure 2.1.3.A. Many countries use graphical charts. These are acceptable provided the identity of the person recording the temperature is noted and provided there is a space on the chart for recording notes. It is essential that this process is not purely mechanical. Staff must be made responsible for their actions, and trained to react effectively to problems as soon as they arise.

Figure 2.1.3.A - Temperature inspection record sheet

Location:	Primary store
Equipment:	Cold room no. 1
Correct temperature range:	+2°C to +8°C
Week commencing Monday:	4th February 2002

Day	A.M.	°C	OK?	Initials	P.M.	°C	OK?	Initials
Mon	7.00	4.0	Yes	AG	17.05	5.0	Yes	EF
Tue	7.15	3.5	Yes	AG	17.00	4.5	Yes	EF
Wed	7.45	4.5	Yes	AG	16.55	5.0	Yes	EF
Thu	7.00	10.0	No	AG	17.10	10.5	No	EF
Fri	6.55	6.5	Yes	AG	17.15	5.5	Yes	EF
Sat	7.05	4.5	Yes	AG	17.00	6.0	Yes	EF
Sun	7.15	4.5	Yes	AG	16.55	5.5	Yes	EF

Fill in this form twice every 24 hours, seven days a week.

1) Check the thermometer and write down the temperature and the time of the inspection.
2) Check the continuous temperature record. Write "Yes" in the OK column ONLY if the temperature has stayed within the correct temperature range since the time of the last inspection. Otherwise write "No" and report this to your supervisor.
3) In the **Notes** section, write down all unusual events, mechanical noises, etc. Report these to your supervisor.
4) Every Monday morning, start a new sheet and give the completed one to your supervisor.

Notes:

- Wednesday p.m. refrigeration unit very noisy.
- Thursday a.m. Refrigeration unit failed. Engineer called.
- Thursday p.m. Unit repaired at 19.00 hrs.

ALWAYS REMEMBER: The person completing this form is responsible for the safety of the vaccine!

Responsible staff should also know what action to take if the temperature at the time of inspection is outside the safe range. Figure 2.1.3.B sets out the appropriate actions under a range of common circumstances.

Figure 2.1.3.B – Some actions to take when the storage temperature is incorrect

Cold rooms and vaccine refrigerators:

- Temperature between +2° C and +8°C. Situation normal, no action necessary.
- Temperature at or below 0°C. **VACCINE AT RISK.** Take immediate action to correct the low temperature and ensure that the problem does not arise again. Inspect the freeze-sensitive vaccines and/or carry out a shake test, as described in Figure 2.1.5.A, to establish if any has been frozen. Frozen vaccine will either have to be destroyed or tested to establish whether it is still potent. Make a report.
- Temperature between +8°C and +10°C. If there has been a temporary power failure, no further action is necessary. Check that the refrigeration unit is working, monitor the situation closely and take appropriate action if temperature is not within the normal range at the time of the next inspection.
- Temperature above +10°C. **VACCINE AT RISK.** Take immediate action to implement the agreed contingency plan, and make a report.

Freezer rooms and chest freezers:

- Temperature between -25°C and -15°C. Situation normal, no action necessary.
- Temperature below -25°C. Adjust thermostat. Check that the temperature is within the normal range at the time of the next inspection.
- Temperature above -15°C. If there has been a temporary power failure, no further action is necessary. A temporary rise to +10°C is permissible following an extended power cut. Check that the refrigeration unit is working, monitor the situation closely and take appropriate action if conditions are not normal at the time of the next inspection.
- Temperature above +10°C. **VACCINE AT RISK.** Take immediate action to implement the agreed contingency plan, and make a report.

Whenever it is suspected that vaccine has been frozen, at least one member of the duty staff should know how to perform and interpret a 'shake test' as described in Figure 2.1.5.A.

Most importantly, all responsible staff should know when and how to respond in the event of equipment failure. Junior staff may simply be required to report to their supervisor. More senior staff should know and understand the contingency plan and should be able to implement it effectively if the need arises.

Figure 2.1.3.C sets out the elements of a typical contingency plan. This will need to be modified to suit local circumstances.

Figure 2.1.3.C – Elements of a contingency plan

Ensure that all staff know how to follow safe storage rules in an emergency:

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

Identify a range of contingency options (the following are four examples:)

- Move the vaccine to another public service cold store.
- Borrow or hire a refrigerated vehicle.
- Move the vaccine to a private sector cold store.
- Obtain ice from a commercial ice maker and store this inside the cold room or freezer room in plastic or metal containers. Closely monitor the room temperature and keep the ice supply replenished until repairs are carried out. *Never* use dry ice. Dry ice may lower the temperature of the cold room to below 0°C. In addition, when it evaporates it gives off carbon dioxide gas; this may build up in the cold room and could suffocate anybody who enters the room.

Prepare and maintain at least two contingency plans based upon these options.

- Whatever plans you choose, make sure they are discussed and agreed beforehand with your staff, and with all the other parties involved.
- Confirm the plan in writing. Keep a copy in the vaccine store. Make sure your staff know where it is.
- Check alternative stores to ensure that they are in good condition, have adequate space and are capable of maintaining vaccine at the correct temperature. There is no point moving stock to another cold room only to find that all your freeze-sensitive vaccine is frozen and destroyed.
- Do not wait until an emergency occurs. Rehearse[a] the plans *before* they are needed.
- Prepare a list of emergency contact names, addresses and telephone numbers and post a copy of the list in the vaccine store. Keep the list up to date.
- Make sure that emergency contacts can be made both inside and outside normal working hours.

[a] Vaccine should not be physically moved during rehearsals, but all key procedures should be simulated.

Record keeping: Maintain training records to show which staff members have received training in vaccine handling, including training in the "shake test". Fill in the temperature inspection record sheets.

Display the contingency plan in a prominent location, including a list of contact names and telephone numbers. Maintain records to show which staff members have received contingency plan training and keep records of training exercises.

Materials and equipment: Temperature inspection record sheets.

2.1.4 Keep temperature records in a safe place for a minimum of three years.

Knowledge and responsibilities: Responsible staff should know how to look after the temperature recording equipment and how to interpret the records produced. Chart recorder discs and pens should be changed at the intervals recommended by the chart recorder manufacturer.

Record keeping: Maintain training records to show which staff members have received training in using and looking after the temperature recording equipment.

All temperature records should be filed in date order and kept for a minimum of three years. Where chart recorders are used, the paper discs should be filed in date order every time they are changed. Where electronic temperature data loggers are used, the data should be printed out at least once a week and filed. Finally, the temperature inspection record sheets should be changed every week and the completed sheets filed.

Materials and equipment: Blank chart recorder discs, spare pens, stationary.

2.1.5 Record all vaccine discarded due to incorrect storage temperatures. Keep the records in a safe place for a minimum of three years.

Knowledge and responsibilities: Responsible staff should understand the purpose of VVMs and the freeze indicators. They should know how to interpret these devices when they change appearance, and what action to take when this happens. Whenever it is suspected that vaccine has been frozen, at least one member of the duty staff should know how to perform and interpret the 'shake test'. Figure 2.1.5.A describes how to undertake this test.

Figure 2.1.5.A – The 'shake test'

Purpose: The **SHAKE TEST** is designed to determine whether adsorbed vaccines (DPT, DT, Td, TT or hepatitis B) have been affected by freezing. After freezing, the lattice (bond between adsorbent and antigen) gets broken. Separated adsorbent tends to form granules and gets bigger in particle size and weight; it gradually settles to the bottom after the vial has been shaken. The size of the granules seems to increase on repeated freezing and thawing cycles. Sedimentation occurs faster in a vaccine vial which has been frozen than in a vaccine vial from the same manufacturer which has never been frozen.

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

Test procedure:

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

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

Every incident involving VVM changes, burst freeze indicators, or frozen vaccine should be recorded in the stock records. Whenever such an event occurs, take immediate action in accordance with Standard Operating Procedures.

In cases where damaged vaccine cannot be used, the stock records should be adjusted and the loss should be recorded on a Loss/ Adjustment report similar to Figure 2.1.5.B. Damaged vaccine should be safely disposed of as described under para. 6.1.7.

Figure 2.1.5.B – Sample loss/adjustment report[a]

LOSS / ADJUSTMENT REPORT **No:** *serial number*

Issuing office: _____

Warehouse: _____

Issued by: _____ Date: _____

Signature: _____

Programme section:

Certified by: _____

Signature: _____

Loss: ☐ Damaged in transit: ☐ Other: ☐

Expired: ☐ Damaged in store: ☐ Explain:

Narrative & recommendation for corrective actions and disposal:

No.	Supply requisition	PO/ Delivery	Item description	Unit	Quantity to be disposed of

Property survey board submission:

List of attached documents to the report (photos, claim, lab analysis, batch and expiry dates, etc.)

Original copy: | Copy 1: | Copy 2: | Copy 3:

[a] Adapted from a standard UNICEF form.

Record keeping: Maintain training records to show which staff members have received training in the use of VVMs and freeze indicators, training in the "shake test" and training in procedures relating to vaccine loss or damage.

All loss/adjustment reports temperature records should be filed in date order and kept for a minimum of three years.

Materials and equipment: Loss/adjustment forms.

2.1.6 *Carry out an internal review of the temperature records and discarded vaccine records every month. Keep temperature review reports in a safe place for a minimum of three years.*

Knowledge and responsibilities: The EPI manager has overall responsibility for the primary store. The EPI manager, or a delegated supervisor, should first of all review the loss/adjustment records to establish if any vaccine has been lost during the review period. He/she should then inspect the temperature records and relevant data from the stock control system and take an informed view on whether any other vaccine may have been exposed to unacceptable risk. Whenever failures are detected, he/she should be able to recommend appropriate action to prevent future failures and have the knowledge and authority to ensure that this action is taken. Figure 2.1.6.A gives an example of a completed review report.

Figure 2.1.6.A – Monthly temperature review report

Location:	Primary store			**Serial no:**	AR02/02
Review period:	1/6/02 to 31/6/02				
Have storage conditions complied with EVSM criterion 2?		**Yes**		**No**	X
Inspector:	A. Senior. Manager				
Date:	8/7/02				
Enter all vaccine losses during the review period which are formally recorded on loss/adjustment reports.					
Equipment	**Date**	**L/A report #**	**Affected vaccine**	**Doses lost**	
Cold room # 1	3/6/02	L/A02/01	HepB	9,500	
Cold room # 1	3/6/02	L/A02/01	DTP	5,500	
etc.					
Record all instances during the review period when storage temperature was outside recommended limits.					
Equipment	**Date**	**Temperature**	**Vaccine at risk?**	**Action taken at time of event**	
Cold room # 1	1/6/02	-1° C	Yes	None	
Cold room # 1	2/6/02	-2° C	Yes	None	
Cold room # 1 L/A # 02/02 raised	3/6/02	-6° C	Yes	Engineer called	
etc					
Narrative: Cold room #1 had a defective thermostat sensor between 1st and 3rd June, resulting in an unacceptable loss of vaccine. On enquiry I found that the duty staff did not know that HepB freezes at -0.5°C so they ignored the sub-zero temperatures on 1st and 2nd June and only notified the storekeeper that there was a problem on 3rd June. The cold room has not yet been fitted with a temperature alarm although this has been on order since April. No other problems were noted during the period.					
Recommendations: Duty staff should receive additional training in temperature monitoring. Until this has been done, the storekeeper should monitor temperatures each day. Temperature alarms should be fitted to cold rooms 1, 2 and 3 and to the three vaccine freezers before 21st July.					
Original copy:	Copy 1:	Copy 2:	Copy 3:		

Record keeping: Keep the monthly audit reports for a minimum of three years, filed in date order.

Materials and equipment: Audit report proformas.

2.2 Temperature recording devices have an accuracy of ± 0.5°C.

Responsible staff for this sub-section: The EPI manager is responsible for ensuring that the accuracy test is carried out once a year.

2.2.1 Provide evidence that temperature recording devices comply with the specified level of accuracy. Carry out this test at least once every 12 months.

Knowledge and responsibilities: The organization or person carrying out the accuracy test should be fully qualified and properly equipped to undertake this task. Suitable candidates could be a government laboratory, a private refrigeration company or a private consultant. Figure 2.2.1.A gives an accuracy test protocol:

Figure 2.1.6.A – Temperature accuracy test protocol

Materials and equipment: Electronic thermometer with thermocouple sensor head calibrated to an accuracy of ± 0.5°C.
Test procedure: Place the sensor head of the electronic thermometer next to the sensor head of the temperature recorder in the cold room/freezer room or in the appropriate position in a vaccine freezer or ice-lined refrigerator. Allowing for the initial stabilization of the thermometer. The two readings should match to within an accuracy of ± 1.0°C.

Record keeping: Keep accuracy test records for a period of three years.

Materials and equipment: Electronic temperature logger calibrated to an accuracy of ±0.5 °C.

3. Maintain sufficient cold store capacity

3.1 The store can accommodate peak stock levels for all the vaccines specified in the national immunization schedule, including campaign vaccines where these are normally kept in the primary store.

Responsible staff for this sub-section: The EPI manager or delegated staff member.

Reference documents for this sub-section:

- *Managing drug supply, 2nd ed.* Kumarian Press, 1997. Chapter 15: *Inventory management.*
- *Guidelines on the international packaging and shipping of vaccines* (WHO/V&B/01.05).
- *Guideline for improving primary and intermediate vaccine stores* (WHO/V&B/02.34).

3.1.1 Carry out vaccine volume estimates for all vaccines, diluents and droppers that are stored in the primary store. Accurately establish the maximum volume of vaccines, diluent and droppers that have to be stored at each of the recommended storage temperatures (-15 to -25 ºC, +2 to +8 ºC, and ambient).

Knowledge and responsibilities: The responsible staff member should know how to estimate the physical volume of vaccine ordered by the programme and how this volume is distributed down the supply chain. In the first instance, this estimate should be carried out for the primary store and for each intermediate store. Ultimately it should be carried out for every other place where vaccine is kept. In order to establish whether peak stock levels can be accommodated, the responsible staff member should first estimate the maximum volume of vaccine that has to be accommodated in the store. Include routine vaccines and any other products that require refrigeration. Also include campaign vaccines where these are kept in the store. To complete this task, establish and record the following data:

- The maximum number of doses of each vaccine that will be stored in each facility at any one time. Roughly speaking, for each vaccine, the maximum number of doses = (annual number of doses required / number of deliveries received per year) + the number of doses in the safety stock. However the result of this calculation needs to be applied carefully. For example, if the various vaccines come from different suppliers, they may not all arrive at the same time. Thus, the peak storage requirement for (say) HepB may not necessarily coincide with the peak storage requirement for other vaccines. In addition, the calculation needs to take account of the delivery schedule for outgoing vaccines dispatched to the lower level stores.

- The stored volume per dose for each vaccine, and for any associated diluents or droppers. This figure varies significantly and depends upon the presentation (single versus multi-dose vials), the source of the vaccine, and the type of packaging in which it is stored. If vaccine is stored in its outer insulated packaging (as is sometimes the case) it is very much bulkier than if it is stored in its inner cartons.

Where diluent is packed with the vaccine, both the diluent and the vaccine will have to be kept cold. Take account of this when calculating the requirement for cold storage. Also take account of the delivery and distribution schedule for each vaccine and the volume of the safety stock that is to be maintained. Base the calculation on the actual volume of each presentation using data supplied by the manufacturer or supplier. Make a reasonable allowance for programme expansion and/or the introduction of new vaccines. The form shown in Figure 3.1.1.A can be used for the calculation.

Figure 3.1.1.A – Form for calculating vaccine and diluent volumes

ITEM:

Storage temperature: -15 to -25ºC ☐ +2 to+8ºC ☐ Ambient ☐ (tick approprate box)

A. Presentation: ☐ doses per vial or ampoule A.

B. Packaging: ☐ vials or ampoules per pack B.

Note: For step C, refer to Table 2 of the *Guidelines on the international shipping of vaccines* (WHO/V&B/01.05) Alternatively, obtain manufacturer's data.

ENTER PACKED VOLUME PER DOSE

C. Volume per dose: = ☐ cm3/dose C.

CALCULATE NUMBER OF DOSES REQUIRED

D. Total doses/year: (from analysis of programme records) = ☐ doses D.

CALCULATE STORAGE VOLUME

E. Annual volume: C ☐ x D ☐ / 1000 = ☐ litres E.

F. Supply interval (enter supply frequency in months): ☐ / 12 = ☐ years F.

G. Safety stock (enter safety stock level in months): ☐ / 12 = ☐ years G.

H. STORAGE VOLUME (litres): E ☐ x (F+G) ☐ = ☐ litres H.

J. STORAGE VOLUME (cubic metres): H ☐ / 1000 = ☐ m^3 J.

K. Transport box grossing factor: BCG, OPV, measles, MMR, MR = 6.0; Other vaccines = 3.0; Diluent,droppers = 1.5 ☐ K.

L. TRANSPORT BOX VOLUME: J ☐ x K ☐ = ☐ m^3 L.

NOTES:
1) Complete one of these worksheets for each vaccine.
2) Complete one of these worksheets for each diluent and for the OPV droppers.
3) Collect the completed worksheets for each of the three storage temperatures and add up the total storage volume required for each temperature.

Record keeping: Data and calculations as indicated above.

Materials and equipment: A computer with spreadsheet software is desirable, but not essential.

3.1.2 Ensure that the net vaccine capacity of the cold storage available exceeds the calculated maximum vaccine volume.

Knowledge and responsibilities: The responsible staff member should know how to estimate the existing storage capacity available at each of the three storage temperatures. These figures can then be compared with the peak stock levels calculated under para. 3.1.1 and this will establish whether adequate storage space is available. Again, this estimate should be carried out for the primary store, for each intermediate store, and, ultimately, for every other place where vaccine is kept.

The following data are needed:

- The net vaccine storage capacity available in each cold room, freezer room, vaccine freezer and vaccine refrigerator within each storage facility. The capacity of most vaccine refrigerators and freezers is given in the WHO/UNICEF *Product Information Sheets*, but the net volume of cold rooms and freezer rooms has to be calculated. This is done by measuring the total net volume of the available shelf space (= length of shelving x space between shelves (including the space available above the top shelf) x depth of shelves). In practice it is not possible to make 100% use of the available volume. A safe assumption is to divide the available storage capacity by 1.5 to arrive at a figure for usable net volume. For example, if after using the above method the net volume of a cold room is calculated to be 4500 litres, the usable volume is probably closer to 4500/1.5 = 3000 litres.
- The net volume available at ambient temperature for the storage of diluents and droppers at each facility. Use the method described above.

Compare the results with the vaccine volume calculations from para. 3.1.1. The net storage volume available at each of the three temperatures should exceed the volume of vaccine to be stored at each temperature. If it does not, then either the delivery interval should be reduced, or additional cold chain equipment should be obtained. A safety margin of 25–100% spare storage capacity is desirable.

Record keeping: Data and calculations as indicated above.

Materials and equipment: A computer with spreadsheet software is desirable, but not essential.

3.2 Where vaccine supplied for campaign use is stored in temporary facilities, these facilities can accommodate peak stock levels.

Responsible staff for this sub-section: The EPI manager or delegated staff member.

Reference documents for this sub-section:

- *Guideline for improving primary and intermediate vaccine stores* (WHO/V&B/02.34).
- *Guidelines on the international packaging and shipping of vaccines* (WHO/V&B/01.05).

3.2.1 Carry out vaccine volume estimates for all campaign vaccines, diluents and droppers that are stored in the temporary facilities. Accurately establish the maximum volume of vaccines, diluent and droppers that have to be stored at each of the recommended storage temperatures (-15 to -25 ºC, +2 to +8 ºC, and ambient).

Knowledge and responsibilities: Using the approach described in para. 3.1.1, the responsible staff member should calculate the physical volume of campaign vaccines that are to be stored in temporary facilities.

Record keeping: Data and calculations as indicated above.

Materials and equipment: A computer with spreadsheet software is desirable, but not essential.

3.2.2 Ensure that the net vaccine capacity of cold storage equipment available exceeds the calculated maximum volume of the campaign vaccines.

Knowledge and responsibilities: Using the approach described in para. 3.1.2, the responsible staff member should assess whether the size of the temporary cold store used for campaign vaccines is adequate. Again, a safety margin of 25–100% spare storage capacity is desirable.

Record keeping: Data and calculations as indicated above.

Materials and equipment: A computer with spreadsheet software is desirable, but not essential.

4. Buildings, equipment and transport

4.1 The store building is suitably sited and is constructed to an adequate standard.

Responsible staff for this sub-section: Property services/maintenance department.

Reference documents for this sub-section:

- *Guideline for improving primary and intermediate vaccine stores* (WHO/V&B/02.34). Sections 6 and 7.

4.1.1 Ensure that the site where the store building is located is accessible to staff and transport and is secure.

Knowledge and responsibilities: The reference document for this section provides a detailed checklist for evaluating potential sites for new vaccine stores. A shortened version is set out in the box below, and this may be used as a basis for a site review:

- Is the building large enough?
- Can delivery vehicles easily reach the store?
- Is the site secure?

Record keeping: Record site evaluations based on the checklist in the reference document.

4.1.2 Ensure that the store building is of permanent construction, in good structural condition and well maintained, and that it is adequately secured against fire and theft.

Knowledge and responsibilities: The responsible person should take action necessary to upgrade unsatisfactory buildings. Poorly constructed and poorly maintained buildings place the vaccine at risk because such buildings are vulnerable to damage in storms and may have little resistance to fire or theft. In many cases, the combined value of cold chain equipment and the vaccine may well be greater than the value of the building which houses it. The reference document contains a detailed checklist for inspecting vaccine store buildings. A shortened version is set out in the box below, and this may be used as a basis for a site review:

- Is the roof leaking?
- Are the external walls free of severe cracks or other major damage?
- Are windows and external doors in good condition and secure (pay particular attention to grilles and/or locks)?
- Are floors dry and reasonably level?
- Is the store free from condensation (condensation damages refrigeration equipment)?
- Is the building fitted with an adequate number of working fire extinguishers?
- Is the standard of the electrical system satisfactory (if possible have the system tested by a qualified electrician and obtain an electrical safety certificate)?
- Is the drainage system working (rainwater and foul drainage)?
- Is the air-conditioning system working (hot climates only)?
- Is the heating system working (temperate and cold climates)?

Record keeping: Assessment checklist.

4.2 Accommodation within the store building is satisfactory.

Responsible staff for this sub-section: EPI manager and/or property services department.

Reference documents for this sub-section:

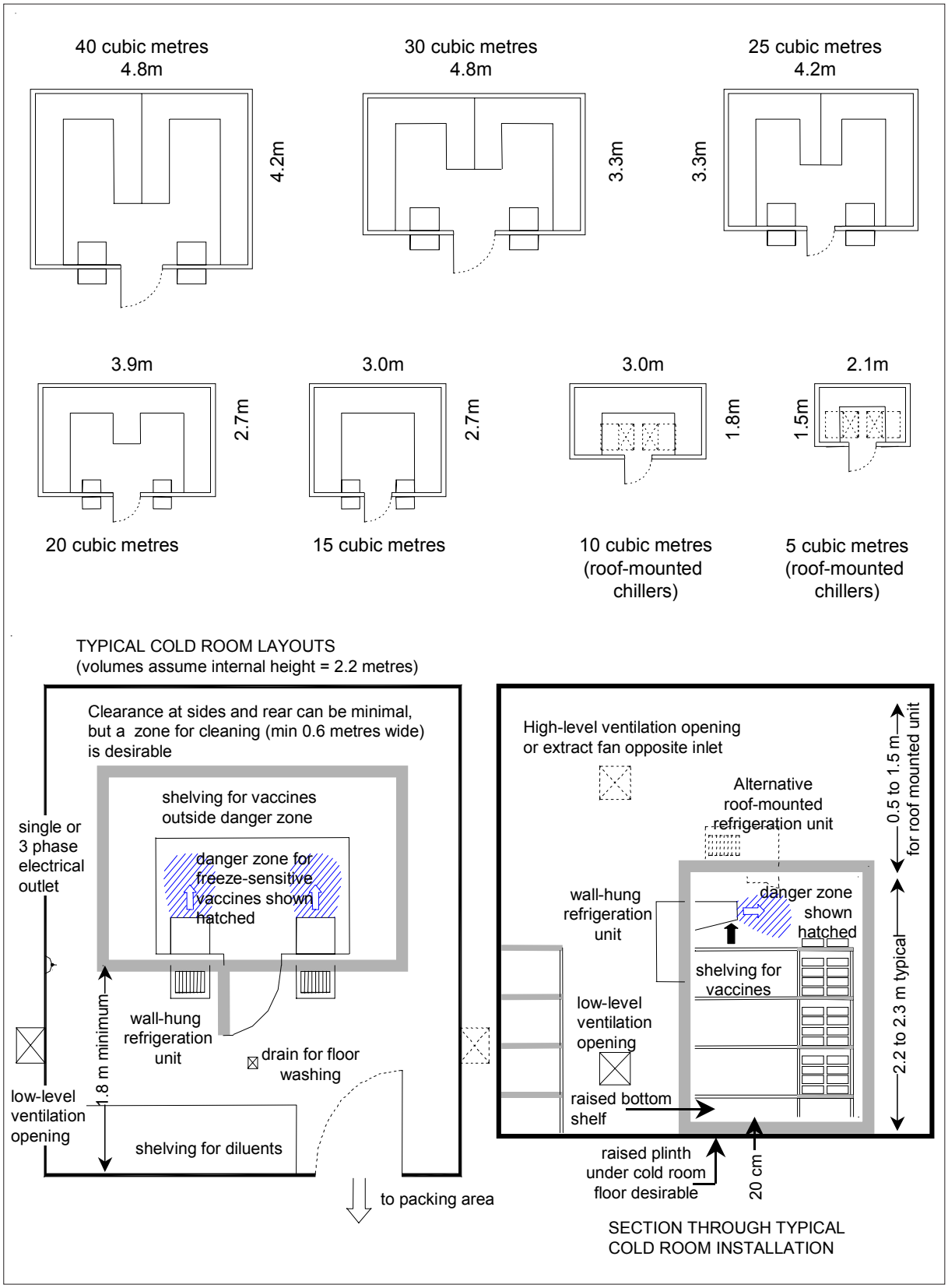
- *Guideline for improving primary and intermediate vaccine stores* (WHO/V&B/02.34). Sections 5 and 7.
- *Ensuring quality of vaccines at country level – A guideline for health staff* (WHO/V&B/02.16).

Generally: A vaccine store needs space for the following: a vehicle loading bay; a room to accommodate the refrigeration equipment; a room to store diluents droppers, packing materials and other consumables such as injection equipment, waste management supplies and spare parts; a room to pack the vaccine for dispatch and an office for the storekeeping staff. Wherever possible, these activities should be housed in the same building, although bulky consumables such as injection equipment and spare parts may have to be stored elsewhere.

4.2.1 Ensure that that the room where the refrigeration equipment is accommodated is large enough. The room should be located close to the packing area and should be adequately ventilated.

Knowledge and responsibilities: Responsible staff should ensure that the room is large enough to give easy access to the refrigeration equipment to enable the equipment to be serviced and maintained. The room should be adequately ventilated. Ideally there should also be sufficient shelving so that diluents can be stored close to the vaccine. Figure 4.2.1A shows how cold stores, vaccine refrigerators and freezers should be organized.

Figure 4.2.1.A – Layout of refrigeration equipment



Record keeping: Assessment checklist.

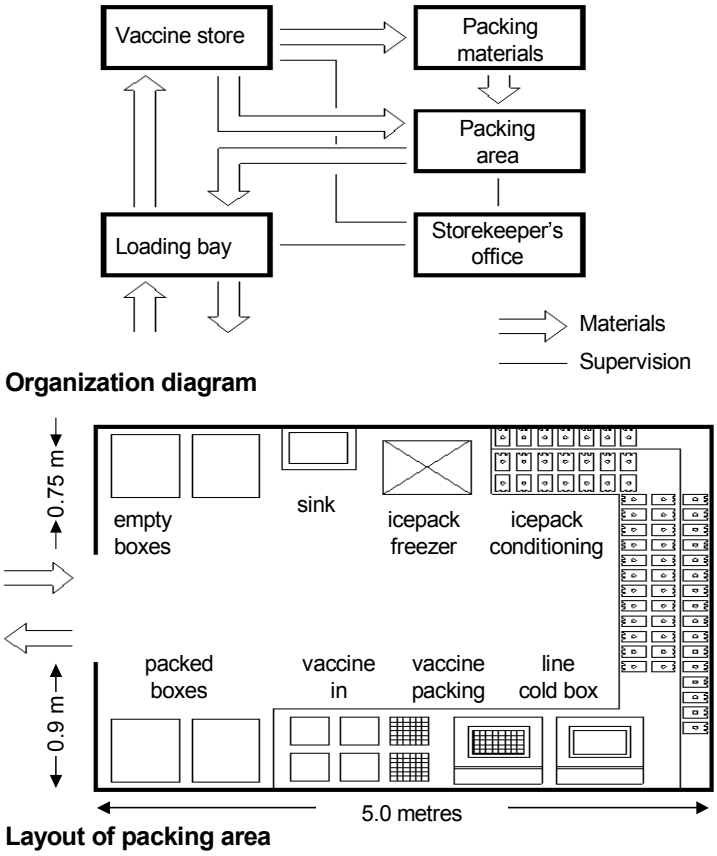
Materials and equipment: Tape measure.

4.2.2 *Provide space for packing vaccine for onward dispatch. Ensure that the packing area is large enough and that it is adequately fitted out and equipped.*

Knowledge and responsibilities: Responsible staff should ensure that the area is large enough to process the maximum daily throughput of vaccine and to accommodate the number of staff employed to pack vaccine for dispatch. 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 (15° to 25°C) when vaccine packing is taking place. Direct sunlight should be excluded from the packing room and ideally there should be no fluorescent lighting. Both sunlight and flourescent light fittings emit ultraviolet light and this can damage vaccines such as BCG, measles, MR, MMR and rubella. Exposure to ultraviolet light also accelerates the reaction of all four types of VVMs.

Vaccine packing involves a number of linked activities. All of these should be accommodated in the same space. Figure 4.2.2.A shows how the packing area should be organized.

Figure 4.2.2.A – Vaccine packing area



Notes:
1. Size of packing area depends upon number of icepacks and icepack freezers required for maximum daily workload.
2. Provide adequate lay out space for icepack conditioning. 25 icepacks require about 1.0m^2 of work space.
3. The vaccine packing room should be air-conditioned in hot climates and heated in cold climates. Working temperature between 15 ºC and 25 ºC.
4. Direct sunlight should be excluded using external shading, curtains or blinds.

Notes:
1. The workshop should be about 0.75 metres above floor level.
2. If additional area is required for icepack conditioning install shelves between 25 to 30 cm wide at 30 cm centres above the work surface.

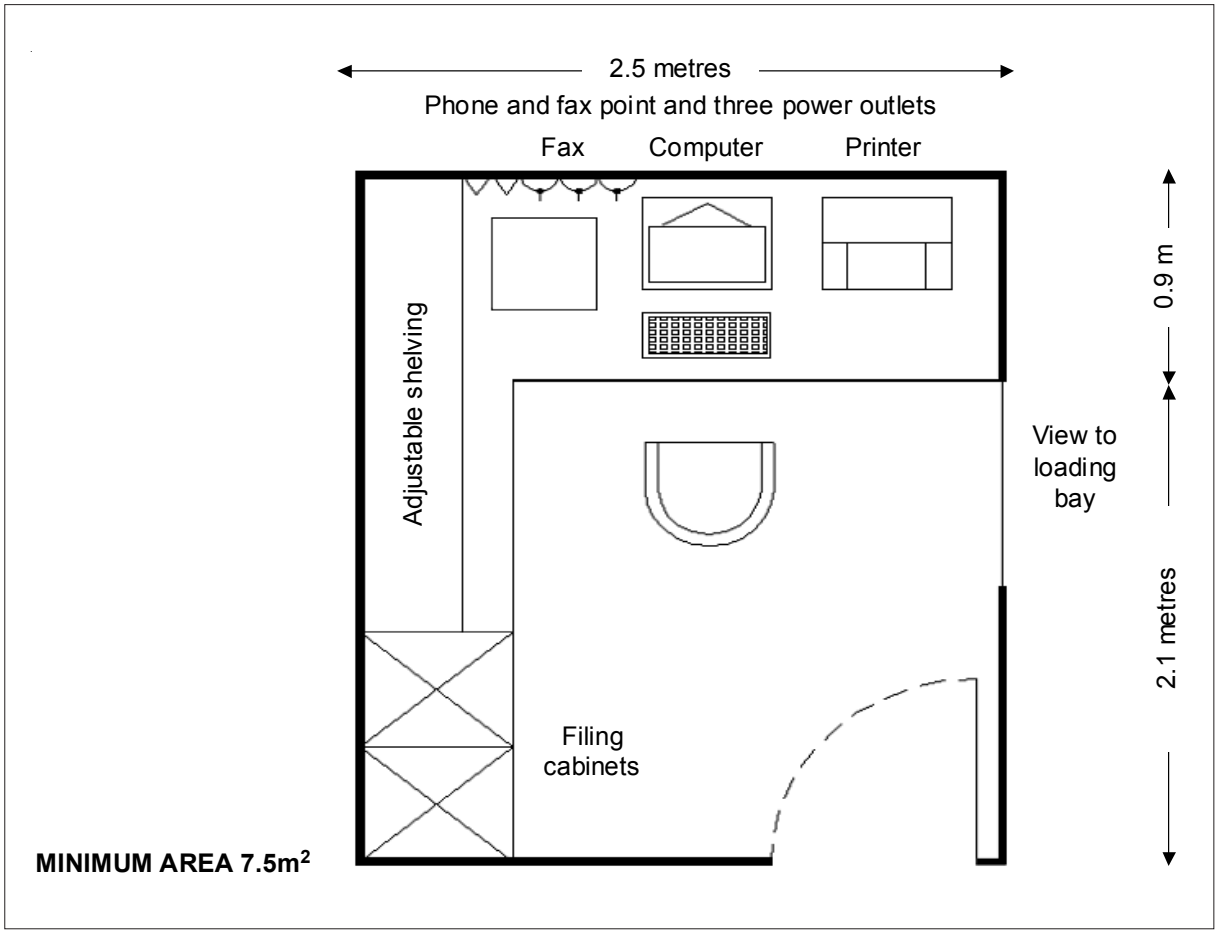
Record keeping: Assessment checklist.

Materials and equipment: Tape measure.

4.2.3 Provide an office for the store keeper. This room should be located close to the refrigeration equipment and the packing room and should be adequately equipped.

Knowledge and responsibilities: Responsible staff should ensure that the storekeeper's office is adequately equipped with work surfaces, shelving and filing cabinets and has sufficient electrical and telephone sockets for the installed equipment (see para. 4.3.9). Figure 4.2.3.A shows a typical arrangement.

Figure 4.2.3.A – Storekeeper's office



Record keeping: Assessment checklist.

Materials and equipment: Tape measure.

4.2.4 Provide storage space for diluents, packaging materials, cold boxes and icepacks.

Knowledge and responsibilities: Responsible staff should ensure that there is sufficient space to store diluents, packing materials, empty cold boxes and icepacks sufficient to supply the needs of the programme. Diluents should be stored as close as possible to the vaccine. Preferably they should be kept in the same room as the refrigeration equipment (see Figure 4.2.2.A). Experience shows that good control of diluent stock is more likely to be achieved when it is stored close to the vaccine to which it belongs – see para. 6.1.5.

Record keeping: Assessment checklist

Materials and equipment: Tape measure.

4.2.5 Special requirements for refrigerated vehicles, where these are used for vaccine delivery.

Knowledge and responsibilities: Some programmes use refrigerated vehicles to distribute vaccine from the primary store. Refrigerated vehicles require specialized facilities and training if they are to be operated safely and effectively. As a minimum, the vehicle must be fitted with a temperature logger. There should also be a weatherproof electrical outlet to power the vehicle's refrigeration unit during loading and unloading operations, and there should be sufficient space to store delivery crates where these are used in place of cold boxes. Temperature control in the refrigerated compartment should be assessed as described in sub-section 2.2.

Record keeping: Data from the vehicle's temperature logger should be kept for a minimum of three years. Retain temperature calibration and training records.

Materials and equipment: Refrigerated vehicle with on-board temperature logger.

4.3 The standard of equipment is satisfactory in both permanent and temporary cold stores.

Responsible staff for this sub-section: EPI manager or delegated staff members.

Reference documents for this sub-section:

- *Equipment performance specifications and test procedures: E1: Cold rooms and freezer rooms* (WHO/V&B/02.33).
- *Guideline for improving primary and intermediate vaccine stores,* Sections 4 and 8 (WHO/V&B/02.34).
- *User's handbook for vaccine cold rooms or freezer rooms,* Section 2 (WHO/V&B/02.31).
- WHO/UNICEF *Product Information Sheets* – current edition.

4.3.1 Cold rooms and freezer rooms should comply with the following minimum standards:

Knowledge and responsibilities: Responsible staff should ensure that all cold rooms and freezer rooms comply with the minimum standards listed below. Ideally they should comply with the current WHO specification – see reference documents:

- Cold rooms should maintain a temperature of +2°C to +8°C in any loading condition between full and empty.
- Freezer rooms should maintain a temperature of -15°C to -25°C in any loading condition between full and empty.
- All rooms should have dual refrigeration units. Each refrigeration unit should be able to maintain the specified temperature independently under all local ambient temperature conditions. Dual refrigeration units ensure that the vaccine remains safe even if one unit fails. Ideally there should be an automatic switchover system to ensure that both units are equally used.
- Doors should be lockable on the outside and open freely from the inside, even when locked. This is an essential health and safety measure to protect workers.
- All rooms should have a continuous temperature recording device and a dial or digital thermometer, both accurate to ±0.5°C.
- Unless they have a digital read-out, temperature recording devices can be difficult to read accurately. A dial or digital thermometer assists with the twice daily checks.
- In cold rooms, the stream of air leaving the evaporator can fall below 0°C until it mixes well with the room air. Vaccine in this zone can freeze. No shelving should be placed in this danger zone. If there is shelving within the danger zone it should either be removed or blocked off with tape or wire mesh.
- The lowest shelf should be at least 200mm above floor level. This keeps the vaccine above the pool of cold air that gathers at the bottom of the room and also prevents it being damaged by floor washing.
- In cold climates. **Either** every cold room should be fitted with thermostatically controlled heater circuits to prevent the room temperature dropping below +2°C; **or** every cold room should be located in a permanently heated room. It is essential that a cold room is not exposed to temperatures below +2°C unless it is fitted with a heater circuit. If there is no heater circuit, and the space outside the cold room is not heated, vaccine will eventually freeze. The heating system must never be turned off at weekends.

Record keeping: Assessment checklist.

Materials and equipment: Cold rooms and freezer rooms, simple tools, tape measure.

4.3.2 Provide adequate protective clothing for staff working in cold rooms and freezer rooms and train staff in safe working practices.

Knowledge and responsibilities: Responsible staff should understand that working in cold rooms and freezer rooms can be dangerous. This is particularly the case in hot climates where people wear thin clothes and may have no experience of intense cold. Staff should be trained in safe working practices and should be supplied with warm jackets, trousers and gloves.

Take these eight precautions:

1) **Tell a colleague what you are doing.** Do not enter a cold room or freezer room on your own without informing a colleague first. If you become trapped in the room you may suffer from hypothermia and you could die.
2) **Check the lock.** Before you enter, check that you have the key and that the door was locked by the last user. Keep the key with you so that you cannot be locked in the room by mistake.
3) **Check the door.** Before anyone enters a cold room or freezer room, check that the door can be opened from the inside.
4) **Cold rooms.** Do not work for any length of time in a cold room unless you are wearing warm clothing. Never remain inside on your own for more than a few minutes. Your body will become chilled and your reactions will become slow.
5) **Freezer rooms.** Never enter a freezer room without wearing protective clothing, including gloves. Never remain inside on your own for more than a few minutes. Your body will become chilled and your reactions will become slow.
6) **Dry ice.** Internationally shipped vaccines may be packed in dry ice. Dry ice changes into carbon dioxide gas when it evaporates. When carbon dioxide accumulates in a confined space it can cause suffocation. If you receive large quantities of vaccine in international shipping containers, do not place these containers in a small cold room or freezer room without removing the dry ice first.
7) **Check the people.** When you enter a cold store with more than two or three colleagues, count the people before they go in and count them again when they come out. Make sure no one is left behind.
8) **Lock the door when you leave**. Lock the door and put the key away in a safe place.

Record keeping: Assessment checklist. Training records.

Materials and equipment: Protective clothing.

4.3.3 Vaccine freezers should comply with WHO specifications and be fitted with a continuous temperature recording device accurate to ±0.5°C.

Knowledge and responsibilities: Responsible staff should ensure that vaccine freezers comply with WHO specifications. Typically equipment will have been selected from one of the many editions of the WHO/UNICEF *Product Information Sheets.* The following are the minimum standards:

- Freezers should be able to maintain a temperature of -15 ºC to -25 ºC in the ambient climate and in any loading condition between full and empty.
- Freezers should be provided with a separate thermometer placed inside the freezer cabinet on top of the vaccine. *Note that the external dial thermometers, which are fitted on many types of vaccine freezer, cannot be relied upon to give an accurate temperature reading*. Preferably each freezer should also be connected to a multi-channel temperature recording device. If this is not possible, then each freezer should be provided with an electronic temperature logger, stored with the vaccine. Data on the logger should be downloaded once a week and printed out. The logger should then be reset and placed back in the freezer. All thermometers and temperature recording devices should be accurate to ±0.5°C.
- It should be impossible to unplug or turn off the power supply to a vaccine freezer by mistake. Directly wired connections into a key operated switch are best, but an adequate compromise is to tape the plug to the wall socket and to tape the switch in the 'on' position. This reduces the risk of unauthorised disconnection.

Record keeping: Assessment checklist.

Materials and equipment: Vaccine freezers.

4.3.4 Icepack freezers should have sufficient freezing capacity to meet the maximum daily demand for icepacks.

Knowledge and responsibilities: Responsible staff should know how to plan and manage icepack freezing and how to establish whether there is sufficient freezing capacity available to meet peak demand. The following checklist outlines the procedure:

- **Calculate volume of vaccine shipment :** Calculate the maximum volume of vaccine to be shipped to the intermediate stores for any one delivery round. This determines the total cold box capacity required.
- **Decide the minimum cold life required:** Consider the length of the journey and the likely effect of travel disruptions due to weather conditions, bad roads or security alerts. This determines the minimum cold life required. Use the worst-case journey time to do this.
- **Select a suitable cold box:** Use the *Product Information Sheets* to select a suitable cold box or to check the performance of existing ones.
- **Calculate the number of cold boxes required:** Assess the number of intermediate stores to be served during a single delivery round. This, together with the volume calculation, determines the number of cold boxes needed.

- **Calculate the number of icepacks:** Based on the choice of cold box, calculate the number of icepacks required for each delivery.
- **Establish the number of icepack freezers required:** Using the worksheet below, calculate the number of icepack freezers required. Icepacks can be frozen rapidly in special purpose icepack freezers and then stored in bulk in domestic chest freezers for subsequent use.

Figure 4.3.4.A – Icepack freezer worksheet

STORE:				
A. Total volume of vaccine delivered and/or collected per year:			litres	A.
B. Deliveries and/or collections per year:			number	B.
C. Average volume of delivery/collection:	A/B		litres	C.
D. Vaccine capacity of cold box (see note 3 below):			litres	D.
E. Average number of cold boxes per delivery/collection (round up result):	C/D		number	E.
F. Icepacks required per cold box (see note 3 below):			number	F.
G. Weight of each icepack (see note 3 below):			kg	G.
H. Maximum number of deliveries and/or collections per 24 hrs (see note 5 below):			number	H.
J. MAX WEIGHT OF ICEPACKS REQUIRED PER 24 hrs (see notes 4 & 5 below):	ExFxGxH		kg	J.
K. Selected equipment:				K.
L. Icepack freezing capacity in kgs/24 hrs (see note 5 below):			kg	L.
M. Number of icepack freezers required (round up):	J/L		number	M.

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

Record keeping: Maintain a record of calculations. Assessment checklist.

Materials and equipment: Icepack freezers.

4.3.5 *The use of CFC gases in refrigeration equipment should be phased out in accordance with UNICEF–WHO policy.*

Knowledge and responsibilities: UNICEF and WHO strongly recommend that all new refrigeration equipment should use refrigerants and insulation foaming agents that meet the requirements of the Montreal Protocol. To this end virtually all the refrigerators and freezers and most of the cold boxes listed in the *Product Information Sheets* are now CFC-free. Similarly, current cold room and freezer room specifications require CFC-free equipment.

Wherever possible, equipment replacement programmes should implement this recommendation.

4.3.6 *There should be a standby power supply for the vaccine store, with automatic start-up. Preferably the generator should serve the vaccine store alone.*

Responsible staff should know how to manage and operate the standby generator. Ideally the generator set should be equipped with an automatic starting device linked to the temperature alarm system in the vaccine store. This reduces the starting frequency in situations where there are frequent power cuts. The following is a checklist of requirements:

- The output of the generator must be sufficient to start all the refrigeration equipment in the vaccine store. Note that the compressor starting load can be five or six times higher than the nominal running load of the equipment.
- Ensure that the generator is in operational order. Run it at least once per week and service it in accordance with the manufacturer's recommendations.
- Ensure that the fuel tank is large enough to enable the generator to run for a minimum of 72 hours without re-fuelling. The maximum running time (in hours) = fuel capacity (in litres) divided by the manufacturer's rated fuel consumption (in litres per hour).
- Supply sufficient fuel and lubricant for the generator. Keep the fuel tank and lubricant topped up.
- The generator and fuel supply should be in a secure compound with fire extinguishers to hand.
- Ensure that fire extinguishers are of the correct type and that they are inspected and refilled at the intervals recommended by the manufacturer.

Record keeping: Assessment checklist.

Materials and equipment: Standby generator and associated equipment, spare parts and consumables.

4.3.7 Provide voltage regulators for all refrigeration equipment wherever voltage fluctuations exceed ±15% of rated voltage (or the refrigeration equipment manufacturer's voltage tolerance, whichever is lower).

Knowledge and responsibilities: Responsible staff should know how to obtain advice on the stability of the power supply. This advice can be obtained from the power authority or from a competent electrical engineer. Regulators are essential wherever voltage fluctuations exceed ± 15%, or exceed the tolerance allowed by the refrigeration equipment manufacturer. If regulators are not fitted, the refrigeration equipment will suffer permanent damage and vaccine may be lost.

Record keeping: Assessment checklist.

Materials and equipment: Voltage regulators.

4.3.8 Temperature alarms should be fitted to all refrigeration equipment used to store vaccine.

Knowledge and responsibilities: Responsible staff should make arrangements for temperature alarms to be monitored 24 hours per day, 7 days a week. All those charged with monitoring the alarm (including night watchmen) must know what action to take to alert a responsible member of the immunization staff if the alarm sounds.

Alarms should be fitted as follows:

- **Cold rooms:** Set to sound in the event of mains failure or when the temperature inside the room is below +2°C or above +8°C.
- **Freezer rooms:** Set to sound in the event of mains failure or when the temperature inside the room is below -25°C or above -15°C.
- **Vaccine freezers:** As a minimum there should be a mains failure alarm on the circuit supplying the freezers. Ideally, each vaccine freezer should be fitted with a temperature alarm which sounds in the event of mains failure or when the temperature inside the freezer is below -25°C or above -15°C.

Preferably alarms should incorporate an automatic dialling device which rings the duty staff members.

Record keeping: Maintain a record of alarm events.

Materials and equipment: Temperature alarms and spare batteries.

4.3.9 National telecommunications links should be sufficient to manage vaccine clearance and distribution.

Knowledge and responsibilities: Staff responsible for clearing shipments do not generally need to make international calls, but they must have access to the national telephone service so that they can communicate with customs staff and with shipping and clearing agents. The storekeeper must be able to communicate with the national EPI manager and with intermediate and other lower level stores.

To achieve this, there should be a direct telecommunications link to the storekeeper's office providing communication with the international airport and with all in-country vaccine stores. Where lower level stores are not connected to the telephone network, there should be a two way radio link.

Record keeping: Assessment checklist.

Materials and equipment: Fax paper, fax cartridges and other communications equipment.

4.3.10 Where a computerized stock control system is used, the software and computer equipment should be suitable for the task and staff should be adequately trained.

Knowledge and responsibilities: Where computers are used, responsible staff should ensure that the storekeeper, or a member of his staff, is trained to be computer-literate and to understand how to interpret data from stock records, temperature data loggers (if used at local level) and the like.

The storekeeper's office should be provided with a computer and printer. The computer should have a back-up facility (floppy drive, zip drive, tape streamer or CD-writer) and be loaded with the following software: word processing, spreadsheet, stock management software (if used), electronic temperature logger software, cold room/freezer room data logger software (if used).

Record keeping: Training records.

Materials and equipment: Computer consumables: paper, printer cartridges, CDs, diskettes, etc., and nationally approved standard templates for letters, reports, forms and the like.

4.4 Satisfactory transport arrangements are in place for moving vaccine from primary storage to intermediate level storage, including arrangements for the maintenance of correct temperatures during transport.

Responsible staff for this sub-section: Immunization staff responsible for transport operations, and drivers.

Reference documents for this sub-section:

- *SCF Transport Management Handbooks,* Save the Children Fund, 1995:
  No. 1: An introduction to the role of field management in the provision and operation of transport
  No. 2: Managing your fleet
  No. 3: Fleet composition and size: replacing or adding vehicles to the fleet
  No. 4: Competence and testing of drivers
  No. 5: Driver's responsibilities
- *Guideline for improving primary and intermediate vaccine stores* (WHO/V&B/02.34).
- *Temperature monitors for vaccines and the cold chain* (WHO/V&B/99.15).

4.4.1 Provide reliable vehicles, with sufficient carrying capacity, whenever vaccines need to be distributed.

Knowledge and responsibilities: Responsible staff should be trained in transport management.

Where vehicles are owned and managed by the immunization programme, and the primary store **delivers** vaccine, carry out planned preventive maintenance on all vehicles in accordance with the recommendations of the vehicle manufacturer. Maintain vehicle logbooks and service records. If an effective transport management system is not in place, then one should be established.

In cases where vaccine is **collected** by the intermediate stores, transport management is not the direct responsibility of the primary store. Nevertheless, where vehicles are owned and operated by others, it is good practice for the primary store to make sure that they are reliable and well maintained.

Record keeping: Training records, vehicle logbooks and vehicle service records.

Materials and equipment: Vehicles and spare parts.

4.4.2 Train drivers how to use vehicles responsibly.

Knowledge and responsibilities: Drivers should be trained how to carry out daily maintenance checks, how to maintain vehicle log books, how to drive safely and how to respond to accidents and emergencies.

Record keeping: Driver training records, vehicle log sheets, accident reports.

4.4.3 Supply fuel and lubricant for all required journeys.

Knowledge and responsibilities: Transport staff should be trained how to control the fuel budget, how to maintain reliable supplies and how to ensure the legitimate use of fuel and lubricant. Drivers should be trained how to record fuel and lubricant use.

Record keeping: Training records, fuel and oil vouchers.

4.4.4 Transport vaccine in cold boxes which have a "cold life" (or in cold climates, a "warm life") sufficient for the longest expected journey.

Knowledge and responsibilities: Responsible staff should know how to pack vaccine for transport and should understand the importance of keeping vaccines at the correct temperature throughout the journey. They should know how to condition icepacks, (or how to use cool packs). In cold climates they should also know how to use warm packs. Drivers should be trained how to protect the vaccine in the event of an emergency, such as a breakdown or an accident.

Conditioning icepacks: Icepacks come out of the freezer at a temperature of about -20°C. They need to be kept at room temperature for a period of time to allow the ice at the core of the icepack to rise to 0°C. This process is called 'conditioning'. The standard advice has been that an icepack is adequately 'conditioned' as soon as beads of water cover its surface. Experiments have shown that this is not always the case and that cold-sensitive vaccines – particularly hepatitis B – can still freeze inside the cold box even when icepacks have apparently been conditioned correctly.

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

- Lay out icepacks, preferably in single rows, but never in more than two rows.
- Leave a 5cm space all round each icepack.
- Wait until there is a small amount of liquid water inside the icepacks. This will take up to one hour at +20°C and rather less at higher temperatures. Shake one of the icepacks every few minutes. The ice is conditioned as soon as it begins to move about slightly inside its container.
- *Transporting vaccine in cold climates:* Field experience in cold climates has shown that it is necessary to protect freeze-sensitive vaccines from exposure to ambient temperatures below 0°C. Where there is a risk of low temperatures during transport, follow the guidelines set out in Figure 1.5.4.A.

Use of chilled water packs: WHO international shipping guidelines (WHO/V&B/01.05) do not require use of icepacks for freeze-sensitive vaccines, although current EPI policy continues to recommend that vaccines should be transported in-country with conditioned icepacks. Unfortunately, evidence from the field indicates a serious problem of compliance with the icepack conditioning recommendations set out above. In order to overcome this problem, WHO has recently carried out tests using chilled water packs instead of icepacks for in-country vaccine transport. These tests have shown that it is quite safe to transport vaccines other than OPV in cold boxes containing chilled water packs at a temperature from +2°C up to +8°C. Transportation with chilled water packs can be repeated for the same vaccines up to four times, each not exceeding 48 hours of delivery time.

By using chilled water packs it is possible to transport freeze-sensitive adsorbed vaccines and measles vaccine in the same cold boxes without significant deterioration in quality. However, in cases where OPV and freeze-sensitive vaccines are packed together, there is NO technology available which provides enough cold for the OPV whilst preventing the freeze-sensitive vaccines from freezing. Consequently, if the decision is taken to use chilled water packs for vaccine transport, OPV should be packed separately and should continue to be transported with icepacks[6].

Record keeping: Training records.

Materials and equipment: Icepacks, freeze indicators.

4.4.5 Where refrigerated vehicles are used to transport vaccine, teach drivers how to use the equipment.

Knowledge and responsibilities: Responsible staff should ensure that drivers know how to operate the vehicle and its equipment and how to safeguard the vaccine throughout the journey. Refrigerated vehicles require specialist knowledge to operate successfully, and they should only be considered in countries which have an adequate service infrastructure.

Where the journey involves overnight stops, the vehicle must be equipped with an auxiliary engine to power the refrigeration unit. Alternatively there must be a suitable electrical supply at each stopping point to power the unit. In cold climates the refrigeration compartment must be fitted with a low temperature heater circuit to provide protection for the vaccine.

Record keeping: Training records.

[6] See also *Monitoring vaccine wastage at country level*, Annex 5 (WHO/V&B/03.18).

5. Effective maintenance

5.1 Planned preventive maintenance to buildings, equipment and transport is carried out.

Responsible staff for this sub-section: EPI manager and delegated staff responsible for maintenance operations.

Reference documents for this sub-section:

- *SCF Transport Management Handbooks,* Save the Children Fund, 1995:
  No. 2: Managing your fleet
  No. 3: Fleet composition and size: replacing or adding vehicles to the fleet
- *Guideline for improving primary and intermediate vaccine stores.* Section 7 (WHO/V&B/02.34).
- *User's handbook for vaccine cold rooms or freezer rooms.* (WHO/V&B/02.31).
- *Managing drug supply, 2nd ed.* Kumarian Press, 1997. Chapter 26: *Transport Management.*

5.1.1 Buildings: *Set up a planned preventive maintenance regime and provide evidence that this plan is being followed.*

Knowledge and responsibilities: Building maintenance is often the responsibility of a specialist property services department. In this case responsible programme staff will only need to know whom to liaise with in this department.

However, where building maintenance is a programme responsibility, then responsible staff should know how to inspect simple buildings, how to instruct and supervise basic building work and how to plan and control a maintenance budget, as outlined below.

Ideally there should be a five year maintenance plan for the vaccine store building(s) which should be updated at least once a year. The plan should include the following elements:

- An itemized maintenance plan, based upon a thorough inspection of the buildings. The plan should cover the following items: major renewal work that can be foreseen, such as re-roofing; periodic external redecoration; periodic internal redecoration; routine annual maintenance of mechanical equipment such as heating systems, air-conditioning units and ventilation fans; periodic maintenance of drainage systems, including cleaning of drainage ditches, septic tanks and the like.
- A maintenance budget (see para. 10.2.3) based upon the requirements of the maintenance plan.

- A financial control and costing system to ensure that funds are disbursed correctly.
- A plan of work which will achieve the targets set in the maintenance plan.
- An effective reporting system.

Record keeping: Training records. Building maintenance plan and maintenance records.

5.1.2 Equipment: *Set up a planned preventive maintenance, overhaul and replacement plan and provide evidence that this plan is being followed.*

Knowledge and responsibilities: Responsible staff should know how to operate the refrigeration, temperature monitoring and alarm equipment, know when routine maintenance is required, and know how to recognize common faults. They should also understand the principles of planned preventive maintenance and routine equipment replacement and their importance for the maintenance of a reliable cold chain.

There should be a five year maintenance and replacement plan for the vaccine store equipment. The plan should include the following elements:

- An itemized preventive maintenance plan covering routine maintenance of cold rooms and freezer rooms in accordance with the manufacturer's recommendations, and the routine replacement of life-limited components, such as filter-driers.
- An itemized equipment replacement plan which will ensure the replacement of refrigeration units, vaccine freezers and icepack freezers before the end of their reliable life.
- A budget (see para. 10.2.4) based upon the requirements of the maintenance and replacement plan.
- A financial control and costing system to ensure that funds are disbursed correctly.
- An effective reporting system.

The plan should allow adequate budget for purchase of spare parts.

If equipment maintenance is contracted out, responsible staff should ensure that an effective and enforceable contract is in place, and that the service response is acceptable.

Record keeping: Training records, equipment maintenance plan, maintenance records and maintenance contract (if applicable).

5.1.3 Transport: *Set up a planned preventive maintenance, overhaul and replacement plan and provide evidence that this plan is being followed.*

Knowledge and responsibilities: Responsible staff should know how to operate a vehicle fleet, know when routine maintenance is required, and know how to recognize common faults. They should also understand the principles of planned preventive maintenance and routine vehicle replacement and their importance for the maintenance of a reliable distribution system.

There should be a five-year maintenance and replacement plan for the transport fleet. The plan should include the following elements:

- An itemized preventive maintenance plan covering routine preventive maintenance; scheduled overhauls, and vehicle replacement based on an agreed replacement policy.
- An itemized vehicle replacement plan, based on an agreed replacement policy, which is designed to ensure that the fleet meets an agreed reliability target (say 95% vehicle availability at all times).
- A budget (see para. 10.2.5) based upon the requirements of the maintenance and replacement plan.
- A financial control and costing system to ensure that funds are disbursed correctly.
- An effective reporting system.

The plan should allow adequate budget for purchase of spare parts.

If vehicle maintenance is contracted out, responsible staff should ensure that an effective and enforceable contract is in place that the service response is acceptable.

Record keeping: Training records, vvehicle maintenance plan, maintenance records and maintenance contract (if applicable).

5.2 Emergency repairs are conducted in a timely manner and are reported.

Responsible staff for this sub-section: EPI manager and delegated staff responsible for maintenance operations.

Reference documents for this sub-section:

- *SCF Transport Management Handbooks,* Save the Children Fund, 1995:
  No. 2: Managing your fleet
- *User's handbook for vaccine cold rooms or freezer rooms* (WHO/V&B/02.31).

5.2.1 Buildings: *ensure emergency repairs to buildings are carried out promptly to avoid risk of damage to vaccine.*

Knowledge and responsibilities: Responsible staff should ensure that day-to-day repairs and renewals are carried out promptly. Such items range from the simple changing of a light bulb through to clearing blocked drains, fixing roof leaks and other similar emergency repairs.

Record keeping: Maintenance records.

Materials and equipment: Simple tools.

5.2.2 Equipment: *ensure emergency repairs to equipment are carried out promptly to prevent risk of damage to vaccine. Where this has not been possible, provide evidence that the contingency plan has been implemented effectively, and in a timely manner.*

Knowledge and responsibilities: Responsible staff should know how to recognize common faults, and they should understand the vital importance of dealing with emergency repairs immediately. They should also know the contingency plan (see para. 2.1.3) and how and when to activate it.

Where equipment maintenance is contracted out, responsible staff should ensure that the emergency response rate is acceptable.

If the planned preventive maintenance regime is effective, emergency repairs should not be needed. However it is absolutely essential that the performance of refrigeration equipment and controls is monitored on a daily basis and that the equipment is repaired as soon as there is any sign of a defect. Use troubleshooting guides to identify the likely cause of the problem and call the service engineer immediately if a defect is identified or suspected. If emergency repairs are a frequent occurrence, this is an indication that the routine maintenance and overhaul regime is not working.

Record keeping: Training records, contingency plan, maintenance records.

Materials and equipment: Simple tools.

5.2.3 Transport: *ensure emergency repairs to vehicles are carried out promptly to avoid risk of damage to vaccine in transit and/or to ensure the vaccine delivery schedule is unaffected. Where this has not been possible, provide evidence that the contingency plan has been implemented effectively, and in a timely manner.*

Knowledge and responsibilities: Drivers, in particular, should know how to respond to emergencies and how to safeguard the vaccine when an emergency occurs – see para. 4.4.2.

If the planned preventive maintenance regime is effective, emergency repairs to vehicles should only be needed in the event of accidents, or mishaps such as punctures. If emergency repairs are a frequent occurrence, this is an indication that the routine maintenance and overhaul regime is not working.

Record keeping: Training records, contingency plan, maintenance records.

Materials and equipment: Simple tools.

5.3 Adequate supplies of spare parts and consumables are available.

Responsible staff for this sub-section: EPI manager and delegated staff responsible for stock management and for maintenance operations.

Reference documents for this sub-section:

- Equipment manufacturer's handbooks.
- Vehicle manufacturers' handbooks.

5.3.1 Buildings: *maintain sufficient supplies of spare parts and maintenance consumables to ensure that the building operates effectively.*

Knowledge and responsibilities: Responsible staff should identify and obtain the range of spare parts and consumables that are required for the vaccine store building. These will include items such as cleaning materials, light bulbs, fire extinguisher refills.

Record keeping: Stock records.

Materials and equipment: Building consumables.

5.3.2 Equipment: *maintain sufficient supplies of spare parts and consumables to ensure that equipment operates effectively.*

Knowledge and responsibilities: Responsible staff should identify the range of spare parts and consumables that are required for the equipment in the vaccine store. In general, follow manufacturer's advice on spare parts inventories. Ensure that items such as spare refrigeration units, compressors, filter driers, refrigerant, temperature recorder discs and pens, freeze indicators, etc. are available. Where there is an equipment maintenance contract, it is possible that some of these parts will be held by the maintenance contractor.

Record keeping: Stock records.

Materials and equipment: Equipment spare parts and consumables.

5.3.3 Transport: *maintain sufficient supplies of spare parts and consumables to ensure that transport operates effectively.*

Knowledge and responsibilities: Responsible staff should identify the range of spare parts and consumables that are required for the vehicle fleet. In general, follow manufacturer's advice on spare parts inventories. Ensure that an adequate supply of spare parts and consumables (e.g. tyres) are kept in stock or can be obtained at short notice. Where there is a vehicle maintenance contract, it is probable that most of these parts will be held by the maintenance contractor.

Record keeping: Stock records.

Materials and equipment: Transport spare parts and consumables.

6. Effective stock management

6.1 Standardized recording and reporting of all stock transactions is carried out. Preferrably this is computerized at the primary level.

Responsible staff for this sub-section: EPI manager and storekeeping staff at the primary and intermediate levels.

Reference documents for this sub-section:

- *Ensuring quality of vaccines at country level - A guideline for health Staff* (WHO/V&B/02.16).

6.1.1 Arrival: *Accurately record incoming vaccines, diluents and droppers and other consumables.*

Knowledge and responsibilities: Responsible staff should understand the importance of accurate record-keeping and should receive training in the use of the stock management system, whether paper- or computer-based.

As a minimum, the following information should be recorded and checked against the VAR (see para. 1.1.1):

- **Vaccines:** quantity (in doses), type, manufacturer, vial size, manufacturing batch or lot number(s), expiry date for each batch or lot, VVM status (1,2,3,4), CCM card status (A,B,C,D) and freeze indicator status.
- **Diluents:** quantity (in doses), type of diluent (e.g. measles 10-dose), manufacturer, manufacturing batch or lot number(s), expiry date for each batch or lot.
- **Droppers:** quantity, type of dropper (e.g. OPV 20-dose), manufacturer, manufacturing batch or lot number(s).
- **Other consumables:** quantity, type, manufacturer and (where relevant) expiry date.

Enter each delivery of each vaccine and diluent in the record system as soon as it is received.

It is advisable to have separate books, ledger sections, or stock cards for each type of vaccine and for each diluent. Where books are used, label each book or ledger section clearly with the vaccine and diluent type. Label it clearly – e.g. "diluent for 10-dose measles vaccine manufactured by XYZ Inc". Where stock cards are used, open a new card for each new delivery and record only one vaccine batch or lot on each card. Again, label each card clearly. Where a proprietary computer-based stock control system is used, either a separate file for each vaccine and diluent type or keep separate sheets for each vaccine and diluent type in the same file.

Make a summary of the amount of each vaccine and diluent received at the end of every month or every three months. Large stores with frequent deliveries to and from the store should complete monthly summaries. Smaller stores with less frequent deliveries will probably find that three-monthly summaries are sufficient. In either case, an annual total for the amount of each vaccine and diluent received must also be made at the end of each year.

During the period that vaccines remain in storage, regularly check the **expiry dates** of the stock to ensure no older batches are present which should have been distributed before more recent arrivals. Also regularly check the **integrity of the stocks** by reviewing the status of the VVMs for each batch or lot. If either of these monitors shows any significant colour change during the period the vaccines have remained in storage, this indicates some weakness in the cold chain system, and repair or maintenance of the cold chain equipment may be needed.

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

Record keeping: Training records, completed vaccine arrival forms and stock records.

Materials and equipment: Standard stock-keeping forms, computer, relevant software, printer, and consumables.

6.1.2 Requisitions: *Operate an effective system for receiving and checking requisitions.*

Knowledge and responsibilities: Responsible staff should know how to process requisitions received from the intermediate stores. They should also know how to check the quantities by comparing them with previous requisitions and with predicted demand. All requisitions should be checked against the agreed distribution plan. Where unexpectedly high or low requisitions are received, these should be queried.

Record keeping: Completed requisition forms.

Materials and equipment: Vaccine distribution plan, standard requisition forms.

6.1.3 Dispatch: *Establish a pre-delivery or pre-collection notification system.*

Knowledge and responsibilities: When vaccines are delivered, responsible staff at the receiving store should know well in advance when the shipment is due to arrive. Establish an effective procedure for doing this. Notification may be by post, telephone, email or fax.

In the case of *deliveries*, the receiving store may need to prepare the store to receive the shipment, for example by re-organizing existing stock to free space in cold rooms and freezers. There must also be an authorized staff member on hand to receive, check and sign for the vaccine.

When vaccines are *collected* from the primary store, staff should know well in advance when the collection is to be made so that they have time to freeze icepacks and to pack the vaccine in preparation for the collection.

Record keeping: Delivery/collection notification records.

Materials and equipment: Notification forms.

6.1.4 Dispatch: *Issue vaccines, diluents and other date-limited products in "earliest-expiry, first-out" EEFO order. If VVM status indicates that some vaccine vials should be used ahead of its correct EEFO order, this may be done, but the reason for doing so should be recorded.*

Knowledge and responsibilities: Responsible staff should know that all vaccines and diluents have an expiry date, after which they must not be used. They should understand that freeze-dried vaccines must always be issued with the correct diluents in matching quantities.

All stocks must be distributed well before their expiry date is reached in order to allow sufficient time for them to pass through the distribution system and to reach the user. Newly arrived stocks will generally have a longer period before expiry than those which have been in storage for some time. Thus, older stocks should normally be distributed first so as to ensure proper rotation of supplies, and to ensure that no batch or lot remains too long in storage. All vaccines and diluents must be systematically arranged in the store so as to facilitate an EEFO stock management system.

During the period that vaccines remain in storage, regularly check the expiry dates of the stock to ensure that older batches are distributed before more recent arrivals. In addition, regularly check the integrity of the stocks by reviewing the status of the VVMs for each vial. If the VVM shows any significant colour change during the period that the vaccines have remained in storage, this indicates a weakness in the cold chain system. Repair or maintenance of the cold chain equipment may be needed. If any freeze indicators have burst this shows a serious failure of temperature control and vaccine may well have been damaged or destroyed.

Heat-exposed vaccine may have to be issued ahead of its EEFO sequence, and in such cases the reason for doing so should be recorded. However, "promoting" vaccine in this way should be done with care because it may cause a displaced batch to reach its expiry date before it can be used.

Incorrect issuing of diluents is a commonly observed system failure. Consignments of freeze-dried vaccine should always be dispatched with the correct quantity of diluent for reconstituting the vaccine. Diluents must always be used with the vaccine for which they are manufactured. Diluents are not all the same, and they must NEVER be interchanged. Careful stock control and accurate records are vital to ensure that the correct diluent is always kept and distributed with each vaccine type and batch.

Record keeping: Completed stock records.

Materials and equipment: Standard stock-keeping forms.

6.1.5 Dispatch: *When vaccines and consumables leave the store, verify the information in the stock record system for all items that are issued. Record any change in VVM status in the stock record system and transfer this information accurately to the vaccine delivery/arrival form.*

Knowledge and responsibilities: Responsible staff should know how to inspect vaccine before dispatch, how to record the transaction in the stock record system and how to complete the delivery section of a delivery/arrival form.

Record the details of each consignment leaving the store in the appropriate ledger, stock book or stock card, and calculate the balance remaining or the "running balance" in stock. Alternatively record the information on the computerized stock recording system, which will automatically recalculate the balance remaining. Do this at the time of distribution to ensure that all details are correctly recorded. For each consignment that is distributed, record:

- **For vaccines, diluents and droppers:** quantity distributed (in doses); destination for the consignment (i.e., name of intermediate store); balance remaining (in doses) of that batch or lot number after subtracting the amount distributed.
- **For consumables:** quantity distributed; destination of the consignment; balance remaining of that product (per batch or lot number where relevant) after subtracting the amount distributed.

All details of the items being distributed should then be written on the delivery/arrival form which will accompany the consignment to its destination (see Figure 6.1.5.A). The receiving store will then know exactly what items are being delivered, and they can then enter the correct details on their own stock record system. The details on the delivery/arrival form should include:

- **For vaccines, diluents and droppers:** Type of vaccine or diluent; quantity distributed (in doses); vaccine/diluent manufacturer; manufacturing batch or lot number(s); expiry date(s) for each batch or lot, and status of the VVMs as the vaccine leaves the store.
- **For consumables:** Type of product; quantity distributed; product manufacturer; manufacturing batch or lot number(s) (where relevant), and expiry date(s) for each batch or lot (where relevant).

Figure 6.1.5.A – Typical delivery/arrival form

Requisition and issue voucher

Voucher no: _____ **Issuing store:** _____ **Ship to:** _____

		Request		Issue					Receive			
Article no	**Commodity name**	**Quantity on hand (doses)**	**Quantity requested (doses)**	**Batch number**	**Expiry date**	**Freeze ind.**	**VVM status**	**Amount (doses)**	**Freeze ind.**	**VVM status**	**Amount (doses)**	**Remarks**
A	B	C	D	E	F	G	H	I	J	K	L	M
1												
2												
3												
4												
5												
6												
7												
8												
9												

Requisition

Requested by: _____
Name: _____
Title: _____
Requisition date: _____
Signature: _____

Issue

Approved by: _____
Name: _____
Title: _____
Approval date: _____
Signature: _____

Shipped by: _____
Name: _____
Title: _____
Shipping date: _____
Signature: _____

Receive

Received by: _____
Name: _____
Title: _____
Receiving date: _____
Signature: _____

Record keeping: Stock records, requisition form, delivery note/arrival form.

Materials and equipment: Standard stock-keeping forms and delivery/arrival forms.

6.1.6 Arrival at intermediate store: *When vaccines and consumables arrive at the intermediate store, check the delivery/arrival form, report any discrepancies and report all indicator changes.*

Knowledge and responsibilities: Responsible staff at the intermediate stores should know how to check deliveries and complete the "arrival" section of a delivery/arrival form. They should know how to interpret VVM and freeze indicators, and what action to take in the event of a change in indicator status during transport.

When a shipment arrives at the intermediate store, follow the procedures outlined in para. 6.1.1. Check indicator status, complete the "arrival" section of the delivery/arrival form and return a copy to the primary store. If the VVM status has changed, ensure that the affected vaccine is used within the prescribed time, or that it is tested. If any freeze indicators have burst, carry out a shake test on the affected vaccine and record the results (see Figure 2.1.5.A). Discard damaged vaccine as described in para. 6.1.8.

Staff at the primary store should investigate the cause of any indicator changes that have occurred during transit and should take any action necessary to prevent a recurrence.

Record keeping: Stock records, delivery/arrival form.

Materials and equipment: Standard stock-keeping forms and delivery/arrival forms.

6.1.7 Disposal: *Safely dispose of damaged or expired stock in accordance with standing orders.*

Knowledge and responsibilities: Responsible staff should know the correct procedures for storing, writing off and safely disposing of expired or damaged stock. Refer also to paras. 2.1.5 and 2.1.6, which describe procedures for recording and accounting for vaccine losses due to incorrect storage temperatures.

Expired vials, heat damaged vials or vials with VVMs beyond the discard point should **not** be kept in the cold store, refrigerator or freezer, as they may be confused with good quality vaccines. If unusable vaccines have to be kept for a period before disposal, for example, until accounting or auditing procedures have been completed, such vials should be kept outside the cold chain, separated from all usable stocks and clearly labeled "*Damaged/expired vaccine – do not use*" to avoid mistaken use.

Similarly, only vaccine stocks which are fit for use should be included in stock records. Damaged or expired vaccines should **not** appear in the available stock balance. If such vaccines do need to be kept until accounting or auditing procedures have been completed, details should be recorded on a separate page or card, pending disposal.

Figure 2.1.5.B shows an example of a loss/adjustment report form.

Once disposal has been authorized, damaged items should be disposed of safely by incineration or other nationally approved means.

Similar rules should be followed for other damaged or expired consumables.

Record keeping: Loss/adjustment report and disposal report.

Materials and equipment: Loss/adjustment forms.

6.1.8 Back up all computer records at least once a week.

Knowledge and responsibilities: Responsible staff should be trained to back up computerized stock records at least once a week. Preferably back-up copies should be kept in a safe place away from the vaccine store.

Record keeping: Back-up discs or tapes.

Materials and equipment: Spare computer media.

6.2 Stocks have been maintained between the safety stock level and the maximum stock level for each vaccine and for other consumables.

Responsible staff for this sub-section: EPI manager and storekeeping staff at the primary and intermediate levels.

Reference documents for this sub-section:

- *Managing drug supply, 2nd ed.* Kumarian Press, 1997. Chapter 15: *Inventory management.*
- *Guideline for improving primary and intermediate vaccine stores* (WHO/V&B/02.34).
- *Guidelines on the international packaging and shipping of vaccines* (WHO/V&B/01.05).

6.2.1 Establish a maximum stock level and a safety stock level for each vaccine and for each consumable. Ensure that it is possible to store the maximum anticipated stock within the facility.

Knowledge and responsibilities: Refer to sub-sections 3.1 and 3.2 for a discussion of this topic.

Record keeping: Stock records.

6.2.2 When orders for new vaccine stocks and consumables are placed, allow sufficient lead-time so as to ensure that each item arrives before the safety stock level for that item is breached.

Knowledge and responsibilities: Responsible staff should know how to monitor stock levels and how to assess whether they are sufficient to meet anticipated demand. They should know the lead time for ordering and delivering each vaccine and consumable and should check these regularly with the suppliers. They should maintain a constant watch on stock levels and ensure that vaccines and consumables are always ordered in good time. Staff should also know how to avoid excessive stock levels. Whilst no vaccine may actually expire in the primary store as a result of excessive inventory, there is a risk that over-stocked vaccine will reach its expiry date before it reaches the end of the supply chain. Refer also to sub-sections 3.1 and 3.2.

A distinction needs to be made here between international vaccine orders and orders placed in-country. In principle, international procurements should always be placed as a SINGLE order with specified split shipment dates. If a country waits until the safety stock level is reached before placing a new order, there will generally not be sufficient lead time to ensure the receipt of new vaccines before a stockout occurs.

Record keeping: Stock records.

6.3 Periodic physical inventories have been conducted.

Responsible staff for this sub-section: Storekeeping staff at the primary and intermediate levels.

Reference documents for this sub-section:

- *Ensuring quality of vaccines at country level – A guideline for health staff* (WHO/V&B/02.16).

6.3.1 Carry out a physical inventory of vaccine, diluent and dropper stocks must be carried out at least once every three months.

Knowledge and responsibilities: Responsible staff should know how to carry out a systematic physical stock count and how to reconcile any errors found in the stock records.

Sometimes errors occur in counting the quantities of vaccines and diluents entering or leaving a store. A regular physical check is the only way to ensure that stock records and running balances are accurate and complete. Count all stocks of every vaccine, diluent or dropper and in storage and compare the totals to those shown as the running balance in the stock records. The count should also match diluents and droppers to the correct vaccine batches.

If the result of counting a stock item is different from that shown in the record, count the stock again to ensure there was no counting error. If a second count gives the same result as the first, the stock record is probably in error, and must be corrected. Take the following action:

- *If more vials are counted than are recorded:* Record the additional amount as a "new arrival" with an explanation of the reason in the notes column of the stock record form.
- *If fewer vials are counted than are recorded:* Record the missing amount as "discarded" with an explanation of the reason in the notes column of the stock record form.

Enter the corrected balance on a separate line in the stock book or card, below the old balance, and write a note with your signature beside it, to indicate that a physical check has confirmed the new balance. Use this corrected total for all future stock calculations. Spot check VVM and freeze indicator status. If any damaged, heat-exposed or cold-exposed vaccines are found in the course of the stock take, set them aside and deal with them as described in 6.1.7.

Physical stock checks should be completed each time a monthly or three-monthly summary is made in the stock book or card (see para. 6.1.1). In addition to monthly or three-monthly checks, an annual physical stock check is also essential.

Record keeping: Stock records.

6.3.2 *Carry out a physical inventory of other consumables (auto-destruct (AD) syringes, safety boxes, temperature recorder charts, forms, stationary, freeze indicators, spare parts, etc.) at least once every three months.*

Knowledge and responsibilities: Follow the procedures set out in para. 6.3.1 for all consumables.

Record keeping: Stock records.

6.4 Good warehousing practices are in place.

Responsible staff for this sub-section: Storekeeping staff at the primary and intermediate levels.

Reference documents for this sub-section:

- *Managing drug supply, 2nd ed.* Kumarian Press, 1997. Chapter 23: *Medical stores management.*
- *Guideline for improving primary and intermediate vaccine stores* (WHO/V&B/02.34).
- *User's handbook for vaccine cold rooms or freezer rooms* (WHO/V&B/02.31).

6.4.1 *Stock security: keep all vaccines and consumables under secure conditions.*

Knowledge and responsibilities: Wherever locks are fitted, doors to cold rooms, freezer rooms, vaccine freezers and store rooms should be locked when not in use. All keys should be kept in a locked key cabinet and accounted for.

Record keeping: Key register.

Materials and equipment: Key cabinet.

6.4.2 *Data security: keep all records secure.*

Knowledge and responsibilities: Records should be kept in locked filing cabinets. The storekeeper's office should be locked when unoccupied.

Record keeping: Key register.

Materials and equipment: Filing cabinet(s).

6.4.3 Storage: store all vaccines, diluents and droppers and other consumables in an orderly fashion.

Knowledge and responsibilities: On general shelving and in cold rooms and freezer rooms, store all items systematically in EEFO order. Clearly label the shelves. In vaccine freezers, store vaccines systematically in EEFO order. Use the freezer manufacturer's wire baskets where these are provided. It is helpful to label the lid of the freezer to indicate its contents.

Materials and equipment: Spare shelf labels (where shelving incorporates a label strip).

6.4.4 Cleanliness: keep the vaccine store clean and free of pests.

Knowledge and responsibilities: Inspect the store regularly. Clean the store two or three times per week. Control pests immediately they appear.

Record keeping: Cleaning rota.

Materials and equipment: Cleaning materials.

6.4.5 Supervision: ensure that all staff are effectively supervised.

Knowledge and responsibilities: Ensure that every member of staff carries out his/her delegated tasks and knows to whom he/she should report. Ensure that adequate supervision takes place. Major breaches of discipline, such as theft or dangerous driving should be dealt with through established procedures.

Record keeping: Staff records.

7. Reliable delivery to intermediate stores

7.1 Distribution reports indicate compliance with the planned delivery schedule.

Responsible staff for this sub-section: EPI manager and senior storekeeping staff at the primary and intermediate levels.

7.1.1 Maintain a programme for the distribution of vaccine from the primary to the intermediate stores. The programme should be flexible enough to accommodate variations in demand from service points.

Knowledge and responsibilities: Responsible staff should know how to establish a realistic delivery programme by analysing past stock records and data from the reporting system. These data should be used to establish a programme for the distribution of vaccines to the intermediate stores (whether by delivery or collection), and to predict future demand.

Record keeping: Delivery programme, stock record system, reporting system.

7.1.2 Maintain an effective reporting system which monitors actual vaccine distributions and compares these with anticipated distributions.

Knowledge and responsibilities: Responsible staff should establish a reporting system which compares anticipated deliveries with requisitions.

Compare predicted need with actual demand. Where figures derived from these two sources conflict significantly, this is an indication that something is wrong. Make enquiries regarding coverage, wastage rates, etc., and establish the cause of the discrepancy. The problem may arise as a result of mismanagement at the periphery (for example, cold chain failures or high wastage rates), or the forecasting system may be wrong. Depending on the nature of the problem, the primary store may risk a stockout or it may find itself holding excess inventory, which may expire before it can be used.

Record keeping: Distribution reports.

7.2 A system for managing short-shipments is in place.

7.2.1 Maintain an effective system for managing short-shipments to intermediate stores

Knowledge and responsibilities: Responsible staff should establish a reporting system for dealing with short-shipments to intermediate stores.

Short shipments can arise for one or more of the following reasons:

- miscounting during assembly of the order ;
- damage due to mishandling during packing or transit;
- shortages at the primary store as a result of delayed deliveries or bad planning;
- poor communications with intermediate stores leading to under-supply (or over-supply). This is particularly likely to occur with a centrally planned "push-down" supply system.

A reporting system should in place to ensure that short shipments are recorded and that all vaccine shortfalls are rapidly followed up and corrected.

Record keeping: Delivery programme, stock record system, reporting system.

8. Minimize damage during distribution

The aim of vaccine distribution management must be to eliminate vaccine losses. Nevertheless, it must be recognized that some wastage may occur as a result of circumstances such as traffic accidents and vehicle breakdowns. Accordingly the Effective Vaccine Store Management initiative has set a target against which programmes will be evaluated. This target is as follows:

In the course of the 12 month evaluation period no more than one percent should have been damaged during distribution from the primary store to the intermediate stores which it serves.

Responsible staff for this section: EPI manager and storekeeping staff at the primary and intermediate levels.

Reference documents for this section:

- *Ensuring quality of vaccines at country level – A guideline for health staff* (WHO/V&B/02.16).

8.1 Freeze indicators are used in all deliveries.

8.1.1 Insert a freeze indicator in every vaccine shipment from the primary store to the intermediate stores.

Knowledge and responsibilities: Responsible staff should know that at least one freeze indicator must accompany every delivery. At the time when the vaccine is packed in the primary store, place it with the most freeze-sensitive vaccine in the shipment. Remove the indicator from the shipment at the time when the vaccine is received by the intermediate store. Record the status of the indicator on the Vaccine Arrival Form (see para. 6.1.5).

Materials and equipment: Freeze indicators.

8.2 In case of failure, damage has been reported and vaccine has been replaced on time.

8.2.1 If the any indicators show exposure to adverse temperatures, check the vaccine and notify the primary store.

Knowledge and responsibilities: Responsible staff should know how to check freeze indicators. If the indicator has "popped" the responsible person in the receiving store should know how to carry out a shake test and should report the results to the primary store immediately. He/she should also know how to check VVMs. If it appears that the vaccine has been exposed to excessive temperatures, notify the primary store immediately. Record all indicator changes on the vaccine arrival form.

Materials and equipment: Vaccine arrival report forms.

8.2.2 Replace damaged vaccine as soon as possible.

Knowledge and responsibilities: Ensure that any damaged vaccine is replaced as quickly as possible so as to avoid shortages.

Materials and equipment: Computerized stock recording system and disposal reports.

9. Effective operating procedures

9.1 Standard operating procedures are in place.

Responsible staff for this sub-section: EPI manager or staff delegated to prepare standard operating procedures.

Reference documents for this sub-section:

- Local procedures and training materials.
- This document and the reference documents referred to therein.

9.1.1 Standard operating procedures should be presented in a form which can be easily understood by the cadre of staff who carry out the procedures.

Knowledge and responsibilities: Responsible staff should assemble a standard operating procedures manual. The standard operating procedures may be developed using the Generic Quality Plan as a guide and should form the basis of a training curriculum, and should be an integrated component of a national cold chain strategy and specification.

Record keeping: Keep records of all changes to standard operating procedures and related training material.

Materials and equipment: Standard operating system manuals.

9.2 Every cold store has a copy of the standard operating procedures, and records are kept as evidence of compliance.

Responsible staff for this sub-section: EPI manager or staff delegated to prepare standard operating procedures.

9.2.1 Standard operating procedures should be supplied to every cold store in a form which ensures that procedures are updated as instructed.

Knowledge and responsibilities: Responsible staff should ensure that each cold store has a copy of all sections of the standard operating procedures that are relevant to that store. A system should be in place to ensure that the document can be updated easily and reliably.

9.3 Staff are trained in the application of the standard operating procedures.

Responsible staff for this sub-section: Staff responsible for in-service training.

9.3.1 Staff should understand the routine day-to-day application of standard operating procedures, including the importance of in-service staff training.

Knowledge and responsibilities: Responsible staff should integrate the routine day-to-day application of standard operating procedures into training materials and training plans. Include references to relevant records, forms and aids, training plans and training materials.

Record keeping: Training materials and training records.

9.3.2 Suitable training aids should be used, which are adapted to the educational level of each cadre of staff.

Knowledge and responsibilities: Responsible staff should ensure that effective and clearly defined training modules are available and that all relevant staff members receive this training.

Record keeping: Training records.

Materials and equipment: Training materials.

10. Financial and human resources

10.1 An annual work plan exists.

Responsible staff for this sub-section: EPI manager or delegated senior staff.

10.1.1 An annual work plan is in existence, which includes the human and financial resource needs of the primary store.

Knowledge and responsibilities: Responsible staff should prepare an annual work plan for the primary store. The plan should start with a "gap analysis" which highlights immediate equipment and vehicle defects and shortages, shortcomings in staff training, personnel shortages, and any other organizational shortcomings which prevent the cold chain from fully meeting the criteria set out in Effective Vaccine Store Management initiative. Based on this analysis, prepare a statement of the improvement and renewal measures needed over the following twelve months, together with an estimate of the cost of these improvements and renewals. The plan should be submitted to government for approval.

Record keeping: Current and previous annual work plans.

10.2 Secured recurrent funding, or secured donor funding, is sufficient.

Responsible staff for this sub-section: EPI manager and government staff responsible for funding and donor relations.

10.2.1 Secured recurrent funding should be sufficient to purchase vaccine, injection equipment and related consumables.

Knowledge and responsibilities: Responsible staff should ensure that sufficient funds are in place to purchase vaccine and consumables. If funds are insufficient, the relevant government departments should be alerted to this.

Record keeping: Budget figures.

10.2.2 Secured recurrent funding should be sufficient to pay and to train staff.

Knowledge and responsibilities: Responsible staff should ensure that sufficient funds are in place to pay and to train staff. If funds are insufficient, the relevant government departments should be alerted to this.

Record keeping: Budget figures.

10.2.3 Secured recurrent funding should be sufficient to maintain equipment.

Knowledge and responsibilities: Responsible staff should secure the budget line necessary to carry out the routine and emergency equipment maintenance referred to in para. 5.2.2.

Record keeping: Budget figures.

10.2.4 Secured recurrent funding should be sufficient to maintain vehicles.

Knowledge and responsibilities: Responsible staff should secure the budget line necessary to carry out the routine and emergency vehicle maintenance referred to in para. 5.2.3.

Record keeping: Budget figures.

10.3 Capital funding, or promised donor funding, is sufficient for the next 12 months.

Responsible staff for this sub-section: EPI manager and government staff responsible for funding and donor relations.

10.3.1 Capital funding should be sufficient to carry out planned equipment replacement.

Knowledge and responsibilities: Responsible staff should secure the budget line necessary to carry out the equipment replacement plan referred to in para. 5.1.2.

Record keeping: Budget figures.

10.3.2 Capital funding should be sufficient to carry out planned vehicle replacement.

Knowledge and responsibilities: Responsible staff should secure the budget line necessary to carry out the vehicle replacement plan referred to in para. 5.1.3.

Record keeping: Budget figures.

10.4 Sufficient qualified staff are employed to operate the store effectively.

Responsible staff for this sub-section: EPI manager and government staff responsible for health service establishment.

Reference documents for this sub-section: None.

10.4.1 There should be the correct number of staff to fill all the posts in the store establishment.

Knowledge and responsibilities: Responsible staff should review staff requirements and advocate for the filling of any gaps.

Record keeping: Staff roster and staff establishment.

10.4.2 These staff should be adequately trained to perform the full range of tasks for which they are responsible.

Knowledge and responsibilities: Responsible staff should prepare training material and conduct effective training sessions.

Record keeping: Training records.

10.4.3 Staff should be adequately motivated so as to ensure that they perform their assigned tasks diligently.

Knowledge and responsibilities: Responsible staff should adopt effective staff management techniques.

10.5 Wherever a service is contracted out, it is adequately funded and resourced and it conforms with the requirements set out in this document.

Responsible staff for this sub-section: EPI manager and government staff responsible for contracted-out services.

10.5.1 Contracted-out services: Where entire services are contracted out and facilities are owned and operated by others, provide evidence to show that a detailed and enforceable contract is in place and that service response is acceptable.

Knowledge and responsibilities: Responsible staff should ensure that, where services are contracted out, there is an enforceable service contract. All facilities, equipment and operational standards should meet the requirements set out elsewhere in this document, and should be inspected.

Port-clearing service: Clearing agent services are discussed under sub-section 1.6.

Vaccine storage and/or distribution service: Some countries contract out vaccine storage and/or vaccine distribution to a commercial company, an non-government organization (NGO), or a parastatal. Where this arrangement is adopted, the immunization service should provide evidence to show that a detailed and enforceable contract is drawn up between the relevant ministry department and the service provider. The contract terms should be drawn up in consultation with the relevant ministry department.

Where a commercial organization is involved, the contract should have been put out to competitive tender. In the case of an NGO or a parastatal, there should be a cost-effectiveness analysis to show that the proposed arrangement is commercially or operationally advantageous.

In all case, clearly defined performance indicators should form part of the contract and the performance of the contracted organization should be effectively monitored by means of a reporting and inspection regime. The conditions of the agreement should be rigorously enforced in the event of poor performance.

Record keeping: Contract agreement, maintenance records and inspection records.

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ORIGINAL: ENGLISH

Module 3

Assessment questionnaire

WHO-UNICEF Effective Vaccine Store Management Initiative

IMPORTANT NOTE: Module 3 provides a printed version of the Excel files to familiarize readers with the structure and content of the forms. All data *must*, however, be entered in the Excel version which contains hidden formulae and different values assigned respectively to the questions. Scores cannot be calculated manually.

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WHO–UNICEF joint statement on effective vaccine store management (WHO/IVB/04.16)
Module 1: Ten global criteria for effective vaccine store management (WHO/IVB/04.17)
Module 2: Model quality plan (WHO/IVB/04.18)
Module 3: Assessment questionnaire (WHO/IVB/04.19)
Module 4: Guidelines for self-assessment (WHO/IVB/04.20)

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Contents

Introduction

The Assessment Questionnaire is the third of four component modules that have been developed by the Effective Vaccine Store Management (EVSM) team, with the aim of helping countries to improve their vaccine storage and distribution systems. The four modules are as follows:

1. **Ten Global Criteria for Effective Vaccine Store Management:** This document describes the background to EVSM and sets out the ten key criteria against which cold store performance is to be evaluated.
2. **The Model Quality Plan:** This document is a reference source. It takes the ten key criteria, breaks them down into sub-headings and supplements these sub-headings with supporting material.
3. **The Assessment Questionnaire:** Initially the Assessment Questionnaire will be used by national inspectors to collect data in a standardized form so that it can be analysed in a consistent manner. Once this exercise has been carried out, and the national team is satisfied that the performance of the store is satisfactory, the national manager can request an international certification inspection based on the same questionnaire.
4. **Guidelines for Self-assessment:** These guidelines are designed to help national managers to assess their own stores, using the Assessment Questionnaire. Once this exercise has been carried out, and the performance of the store is shown to be satisfactory, the national manager can request an international inspection.

Design of the questionnaire: The questionnaire consists of a set of linked Excel worksheets. All cells, other than the commentary and the response cells are protected and should not be altered. Critical indicators are highlighted in colour. Cells containing formulae are generally shaded grey.

Using the questionnaire: As much data as possible should be collected before the assessment takes place. The "Background" and "Human resources" worksheets provide checklists of information that should be obtained and studied before the assessment visit. Worksheets C1 to C10 set out the key questions relating to each of the Ten Global Criteria. The order in which worksheets C1 to C8 are completed is not significant. Worksheets C9 and C10 do not contribute to the score on the radar chart. Many of the questions on these two worksheets are best answered by commentary. In addition the questions in C10 deal with issues of policy and financial management. These questions should be addressed to senior staff and may best be left until the end of the assessment exercise.

Scoring: Most of the questions require a numerical score. With the exception of a few critical indicators, which are weighted, the answers all carry the same value. However the design of the questionnaire allows weightings to be adjusted in future in the light of experience in the use of the tool. The spreadsheet has been designed to enable weighted scores to be changed.

Commentaries: The individual questions, with their numerical answers, cannot hope to capture many of the subtler observations of a skilled assessor. Consequently each sub-criterion has a commentary box after each question or group of questions. These commentaries are an essential part of the assessment. They also provide a place to record the assessors' recommendations for improvements to observed practices.

Error messages: A number of cells in column F of worksheets C1 to C10 also contain error-checking routines. These are designed to ensure that the user does not enter obviously incorrect data (for example in C4:Q16 if a larger number is entered in Q16B than in Q16A this would be illogical. There cannot be a greater number of cold rooms fitted with voltage regulators than there are cold rooms to fit them to). When such an error occurs the word "Check" appears, the cell is highlighted in magenta and the user should review the values just entered before continuing.

Feedback: Both national and international assessors are strongly encouraged to provide feedback to WHO on the use of the tool and to provide suggestions for improvements.

Zoom setting: The width of all worksheets is designed to fill a 1600 x 1200 pixel laptop display at a zoom setting of 100%. The zoom setting will have to be adjusted for lower resolution screens.

Software format: The spreadsheet is issued in Excel 97 format; it will *not* operate in Excel version 4 format or earlier, as these versions do not support multiple worksheets.

Security, setup and general notes:

a) The spreadsheet is supplied with all data entry cells blank, all other worksheet cells "locked". To remove the "read-only" status, save a working copy of the CD original for use on each project. The worksheets in the working copy will remain "locked"– see b) below.

b) There is no password protection on the worksheet "lock" so users can go to Tools/Protect and unprotect an individual worksheet if they so wish. Do not do this unless you wish to see or modify the underlying algorithms otherwise you risk corrupting the worksheet.

c) Only white cells are "unlocked" for selection by the user.

d) To remove any unwanted data in the white cells simply highlight the cell or range and press "delete".

Printing: To print the entire workbook choose File/Print and click "Entire workbook". The spider graph will not be printed. The chart has to be printed separately.

Section A: Background

Note to external assesors: Module 3 provides a printed version of the Excel files to familiarize readers with the structure and content of the forms. All data ***must***, however, be entered in the Excel version which contains hidden formulae and different values assigned respectively to the questions. Scores cannot be calculated manually.

Obtain as much of this information as possible before the inspection commences, including copies of previous self-assessments and previous external assessments.

A1 General details

A1.1	Country:						
A1.2	Department/ministry:						
A1.3	Address:						
A1.4	Primary contact:						
A1.5	Telephone:						
A1.6	Fax:						
A1.7	Email:						
A1.8	Period assessed:	From:		To:			
A1.9	Type of assessment:	Self-assessment:		External assessment:			
A1.10	Dates of assessment:	From:		To:			
A1.11	Self-assessment team:	Min. of Health:		UNICEF rep:		WHO rep:	
	OR						
A1.12	External assessment team:						

A2 Store details

A2.1	Cold store:	
A2.2	Address:	
A2.3	Primary contact(s):	
A2.4	Telephone:	
A2.5	Fax:	
A2.6	Email:	

A3 Background materials requested and obtained before inspection (yes/no answers)

		Requested	Obtained
A3.1	Immunization schedule:		
A3.2	Vaccine supplier(s):		
A3.3	Climate: obtain maximum and minimum annual temperatures at the primary store site:		
A3.4	Standard Operating Procedures manual including copies of standard forms, etc.:		
A3.5	National quality plan:		
A3.6	Details of stock control system used:		
A3.7	Inventory of refrigeration equipment in the primary store, including name of supplier(s).		
A3.8	Inventory of transport fleet including vehicle models and years:		

A4 Details of previous self-assessments and previous external assessments

A4.1	Previous assessments:	Type of assessment:		Date:		Outcome:
		Type of assessment:		Date:		Outcome:
		Type of assessment:		Date:		Outcome:
		Type of assessment:		Date:		Outcome:

Section B: Human resources and service providers

Note to external assesors: Obtain as much of this information as possible before the inspection commences (especially for Section B3).

B1 Permanently employed staff in the vaccine store

List all permanently employed members of staff, including managers, storekeepers, administrators, drivers, cleaners, etc.

	Name	**Job title**	**Qualifications** (see note 1)	**Experience** (see note 2)	**Years in post**
B1.1					
B1.2					
B1.3					
B1.4					
B1.5					

Add further fields as required

B2 Government-employed specialists whose services are available to the vaccine store

List all specialist staff whose services can be called upon (e.g. electrical engineers, mechanical engineers, refrigeration technicians and the like).

	Name	**Job title**	**Qualifications** (see note 1)	**Experience** (see note 2)	**Years in post**
B2.1					
B2.2					
B2.3					
B2.4					
B2.5					

Add further fields as required

B3 Logistics and maintenance service providers

List organizations and companies that provide a logistics service to the programme. If the service is provided by the government, specify the relevant agency/department.

	Service	Organization	Is there a formal contract agreement? YES/NO	If YES, record contract start & end dates	If NO, record how service is procured
B3.1	Building maintenance				
B3.2	Vehicle maintenance				
B3.3	Refrigeration maintenance				
B3.4	Generator maintenance				
B3.5	Clearing agent				
B3.6	Storage service				
B3.7	Transport service				
B3.8	Insurance agency				
B3.9					
B3.10					

Add further fields as required

Notes:

1) Qualifications: Specify level of education: e.g. technical college vocational qualification, university first degree etc.
2) Experience: In particular record previous experience in the field of vaccine management.

Section C: Assessment forms

C1 Over a period of 12 months, pre-shipment and arrival procedures have ensured that all shipments were in satisfactory condition when received by the primary stores.

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
1.1	***The requirements set out in the vaccine arrival report have been complied with for all shipments.***			
1.1.1	Use the standard UNICEF Vaccine Arrival Report (VAR) form wherever possible.	**Method:** Inspect VARs and temperature logger records for the review period.		
		Q1: ***Critical indicator:*** Does the local VAR form include all key procedures from UNICEF VAR Parts I to VII? [YES=1, NO=0. If no VAR of any kind, score 0.]		0.00
		If the answer to Q1 is NO, score Q2 as 0.		
		Q2: ***Critical indicator:*** Assess vaccine arrival reports (VARs) received during the review period:		
		A. How many individual vaccine **arrivals** have there been ?		
		B. There should be a VAR accompanying each individual vaccine. Record the number of VARs that were actually received.		
		C. Record how many of these received VARs were completed substantially correctly by the 'Inspection Supervisor' (see note 1)		0.00
		Commentary:		
1.1.2	Take immediate action if a shipment arrives in the primary store in unsatisfactory condition, or if vaccine arrival procedures have not been followed correctly.	**Method:** Inspect VARs and follow-up correspondence.		
		Q3: Of the individual vaccine arrivals received during the review period (see Q2.A):		
		A: How many were in unsatisfactory condition when they arrived (note 2)?		
		B: How many of these unsatisfactory shipments where followed up with the supplier within 14 days of arrival at the port of entry?		
		Q4: Of the individual vaccine arrivals received during the review period (see note 3):		
		A. How many VARs record that the accompanying paperwork was incomplete?		
		B. How many of these where followed up within 14 days of arrival at the port of entry?		
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
1.2	***Lot release certificates for all shipments are in possession of the NRA and/or the EPI manager.***			
1.2.1	All vaccine shipments are to be accompanied by a lot release certificate (one per lot) issued by the National Regulatory Authority of the country of origin.	**Method:** Inspect Lot Release Certificates received from the NRA of the country of origin. Note that Lot Release Certificates and associated paperwork should be kept for a minimum of five years.		
		Q5: Assess international lot release procedures during the review period. ***Enter 'yes' if vaccine is obtained from UN sources. Enter 'no' if it is obtained from non-UN sources and go to Q6***:		
		A. Referring to Question 2, how many individual vaccine **lots** were received during the review period?		
		B. There should be a lot release certificate from the NRA in the country of origin for every lot received. Record the number actually received.		0.00
		Commentary:		
1.2.2	The National Regulatory Authority in the receiving country should undertake lot release procedures for all vaccines that are obtained from non-UN sources, including all vaccines produced and used within the receiving country.	**Method:** Inspect Lot Release Certificates received from the national NRA. Note that Lot Release Certificates and associated paperwork should be kept for a minimum of five years. (Note: This question is not applicable in cases where the NRA relies on UN purchases and performs only the first two (of six) NRA functions)		
		Q6: Assess national lot release procedures during the review period:		
		A. Referring to Question 2, how many individual vaccine **lots** were received during the review period?		
		B. There should be a lot release certificate from the NRA in the receiving country for each lot. Record the number actually received.		0.00
		Commentary:		
1.3	***Wherever applicable, reliable arrangements have been agreed with the relevant authorities to clear vaccines through customs.***			
1.3.1	Establish effective working arrangements with the customs authorities and with the NRA.	**Method:** Review the working arrangements (and the Memoranda of Understanding (MoU) if it exists). Inspect customs facilities and interview senior customs and NRA staff.		
		Q7: Are any vaccines supplied from an international source or sources? ***[If YES, enter 'yes' and complete remaining questions. If a national supplier is used enter 'no' and answer Q8 NRA question, Q13, Q14 and Q15. Ignore Q9, Q10, Q11, Q12, Q16 and Q17].***		
		Q8: Are the working arrangements with customs and/or the NRA satisfactory? Do any MoUs exist? If so, are they adequate and are the agreed procedures followed?		
		Commentary only:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
1.4	***Wherever applicable, satisfactory procedures/facilities exist for ensuring the integrity of vaccine during clearance.***			
1.4.1	Ensure vaccine is cleared through customs without exposing it to adverse temperatures	**Method:** Review customs clearance procedures. Inspect store, interview staff responsible for vaccine handling.		
		Q9: Have (customs) staff received training in how to look after vaccine? [YES=1, NO=0]		0.00
		Q10: Is a satisfactory contingency plan in place in case: 1) flights are delayed; 2) the airport cold room has failed or 3) transport to the primary store is delayed? [YES=1, NO=0]		0.00
1.4.2	Ensure that the equipment and monitoring procedures in the holding store are satisfactory.	**Method:** If clearance takes more than 24 hours, establish whether there is a cold room at the clearance facility. (Note that clearance could take place at the primary store, in which case score Q8 to Q13 as for the primary store).		
		Q11: Does clearance take more than 24 hours? ***[If YES, enter 'yes' and complete Q12, otherwise enter 'no' and go to Q13].***		
		Q12: Assess cold room facilities:		
		A. Is a +2 ºC to +8 ºC cold room available to hold vaccine during customs clearance? [YES=1, NO=0]		0.00
		B. Is the cold room large enough to accommodate the largest anticipated vaccine shipment? [YES=1, NO=0]		0.00
		C. Does the cold room have a continuous temperature recording device? [YES=1, NO=0]		0.00
		D. Does the cold room have a secure lock? [YES=1, NO=0]		0.00
		E. Is the temperature monitored twice every 24 hours, 7 days a week? [YES=1, NO=0]		0.00
		Commentary:		
1.5	***Satisfactory arrangements are in place for transporting vaccine to primary storage, including arrangements for the maintenance of correct temperatures during transport.***			
1.5.1	Ensure that reliable transport is available to move vaccine from the holding store to the primary store.	**Method:** Inspect vehicles, logbooks and service records.		
		Q13: Are the vehicle(s) in good mechanical condition? [YES=1, NO=0]		0.00
		Commentary:		
1.5.2	In hot climates do not expose shipping containers to excessive temperatures during transport. In cold climates, do not expose shipping containers to temperatures below 0 ºC during the journey. If necessary, use warm packs to protect freeze-sensitive vaccines.	**Method:** Establish whether effective training has been carried out. Interview selected staff to establish understanding of vaccine packing and transport procedures.		
		Q14: Have staff received effective training in vaccine transport? [YES=1, NO=0]		0.00
		Q15: Do staff protect shipping containers against extreme temperatures (hot or cold) ? [YES=1, NO=0]		0.00
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
1.6	***Where a clearing agent is used, the facilities and performance of the agent have been adequately monitored.***			
1.6.1	Draw up a written contract with the clearing agent.	**Method:** Inspect contract.		
		Q16: Is the contract agreement with the clearing agent satisfactory? [Assess contract on a scale of 0= absent to 4= excellent and enter figure in assessment results column. ***Score 'n/a' if no clearing agent is used.***]		0.00
		Commentary:		
1.6.2	Monitor the performance and facilities of the clearing agent and monitor temperature records.	**Method:** To the extent that the clearing agent performs some or all of the tasks listed in 1.1 to 1.5 above, assess the agent's performance against the relevant questions.		
		Q17: Are the facilities and the management performance of the clearing agent satisfactory?		
		Commentary only:		

CRITERION 1 SCORE:	**0.00**
Maximum score:	**22.00**
Percentage score:	**0%**

Notes:

1) Q2: 'Substantially correct' completion means that Part III to Part VII must have been completed in full. It is somewhat less important that Parts I and II have been completed. 'Inspection Supervisor' is the term used in the UNICEF VAR.

2) Q3: 'Unsatisfactory condition' in this context means that the accompanying shipping indicators showed evidence of exposure to excessive heat or cold (UNICEF VAR Part V), and/or that the shipment was physically damaged (UNICEF VAR Part VI). If no unsatisfactory shipments were received, this question is automatically excluded from the total.

3) Q4: 'Accompanying paperwork' in this context must include the following: Airway Bill (or Waybill for local suppliers), Packing List, Invoice and Lot Release Certificate from the NRA in the country of origin (UNICEF VAR Part IV). Omission of any of these items indicates that the paperwork is incomplete.

C2 Over a period of 12 months, all vaccines have been stored within WHO recommended temperature ranges.

Note to assessors: There are a number of unforseeable ways in which vaccine may be damaged or lost during storage which do not necessarily reflect badly on the system - for example, accidental damage during handling. To take account of such events, question **Q5** allows a percentage loss without prejudicing the overall score. However, where such losses have occurred, it is essential that the assessors inquire as to the cause(s) and record this in the commentary. If the main reason for the loss is a system failure then this should be stated and may be used as justification to downgrade the score.

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
2.1	***Continuous temperature records are available, and these records demonstrate that vaccine has been stored correctly in both permanent and temporary cold stores.***			
2.1.1	Store all vaccines and diluents at the correct temperature	**Method:** Interview staff, inspect training records		
		Q1: ***Critical indicator:*** Does the storekeeper know the correct storage temperature range for each of the vaccines on the schedule (see note 1)? [YES=1, NO=0]		0.00
		Q2: ***Critical indicator:*** Does the storekeeper know which vaccines on the schedule will freeze at temperatures below 0 ºC? (see note 2)? [YES=1, NO=0]		0.00
		Q3: Has the storekeeper received formal or on-the-job training in how to look after vaccines? [YES=1, NO=0]		0.00
		Q4: Have all other staff who are responsible for looking after vaccines received such training? [YES=1, NO=0. If no other responsible staff, enter 'n/a']		0.00
		Commentary:		
2.1.2	Use stock records to demonstrate that all vaccines and diluents have been stored in accordance with current WHO storage temperature recommendations.	**Method:** Inspect stock records		
		Q5: ***Critical indicator.*** Collect the following information to establish the percentage of doses of OPV vaccine that have been discarded as a consequence of incorrect storage conditions in freezers or freezer rooms during the review period (note 3).		
		A. Record number of doses of OPV in stock at the start of the review period.		
		B. Record number of doses of OPV received during the review period.		
		C. Record number of doses of OPV issued during the review period.		
		D. Record number of doses of OPV discarded because of incorrect storage temperatures.		
		E. Record number of doses of OPV in stock at the end of the review period.		
		END BALANCE CHECK: Stock records appear to tally		
		F. If the percentage discarded is greater than 1% score is set = 0. If equal to or less than 1%, score = 5.		
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
		Q6: ***Critical indicator.*** Collect the following information to establish the percentage of doses of a selected freeze-sensitive vaccine that have been discarded as a consequence of incorrect storage conditions in freezers or freezer rooms during the review period (note 3). Enter choice of vaccine in the box below:		
		A. Record number of doses of vaccine in stock at the start of the review.		
		B. Record number of doses of vaccine received during the review period.		
		C. Record number of doses of vaccine issued during the review period.		
		D. Record number of doses of vaccine discarded because of incorrect storage temperatures.		
		E. END BALANCE: Record number of doses of vaccine in stock at the end of the review period.		
		END BALANCE CHECK: Stock records appear to tally		
		F. If the percentage discarded is greater than 1% score is set = 0. If equal to or less than 1%, score = 5.		
		Commentary:		
2.1.3	Inspect temperature records at least twice every 24 hours, 7 days per week. Maintain a contingency plan.	**Method:** Inspect temperature record sheets. Inspect recorder data and compare with temperature record sheets. Query sheets that show suspicious uniformity as this may indicate that staff are not actually checking temperatures. Interview staff.		
		Q7: Is there a complete set of manual temperature records for each and every cold room, freezer room and freezer throughout the review period (see MQP Fig 2.1.3.A and note 3)? [YES=1, NO=0]		0.00
		Q8: Is there a complete set of temperature recorder traces for each and every cold room, freezer room and freezer throughout the review period (see MQP Fig 2.1.3.A and note 3)? [YES=1, NO=0]		0.00
		Q9: Does a sample of temperature recorder traces for each appliance agree with the matching temperature records (see note 4)? [YES=1, NO=0]		0.00
		Commentary:		
		Q10: ***Critical indicator:*** Contingency planning - see MQP Fig 2.1.3.C:		
		A. Is there a satisfactory contingency plan in the event of equipment failure? [YES=1, NO=0].		
		B. Was the plan rehearsed at least once during the review period? [YES=1, NO=0].		
		C. Are emergency contact details posted in the vaccine store? [YES=1, NO=0].		
		D. Do staff know what to do in the event of an emergency? [YES=2, NO=0].		0.00
		Commentary:		
2.1.4	Keep temperature records in a safe place for a minimum of three years.	**Method:** Inspect temperature records.		
		Q11: Have temperature records been kept for at least three years, or, if for a lesser period, since the immunization programme adopted the EVSM (see note 5)? [YES=1, NO=0]		0.00
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
2.1.5	Record all vaccine discarded due to incorrect storage temperatures. Keep the records in a safe place for a minimum of three years.	**Method:** Inspect stock records and disposal reports.		
		Q12: Do the quantities of discarded vaccine recorded on the vaccine loss and damage records match losses recorded in the stock records during the review period? [YES=1, NO=0. Score n/a if no losses.]		0.00
		Q13: Have records of discarded vaccine been kept for at least three years, or, if for a lesser period, since the immunization programme adopted the EVSM (see note 5)? [YES=1, NO=0. Score 1 if a recording system exists but no losses occurred during the period. Score 0 if no recording system exists.]		0.00
		Commentary:		
2.1.6	Carry out an internal review of the temperature records and discarded vaccine records every month. Keep temperature review reports in a safe place for a minimum of three years.	**Method:** Inspect monthly temperature review reports (add note re type of report).		
		Q14: Are internal reviews of temperature records carried out at least once every month? [YES=1, NO=0]		0.00
		Q15: Are internal reviews of vaccine loss/damage records carried out at least once every month? [YES=1, NO=0]		0.00
		Q16: Have temperature review reports been kept for at least three years, or, if for a lesser period, since the immunization programme adopted the EVSM (see note 5)? [YES=1, NO=0]		0.00
		Commentary:		
2.2	***Temperature recording devices have an accuracy of +/-0.5 °C.***			
2.2.1	Provide evidence that temperature recording devices comply with the specified level of accuracy. Carry out this test at least once every 12 months.	During the review period, was a temperature accuracy test been carried out for every cold room, freezer room, freezer and refrigerated vehicle (if used)? [YES=1, NO=0]		
		Q17: Does your accuracy test for each appliance agree with the temperature recorder trace for the same time period to within +/-1 °C? [YES=1, NO=0]		0.00
		Commentary:		
			CRITERION 2 SCORE:	**0.00**
			Maximum score:	**37.00**
			Percentage score:	**0%**

Notes:

1) Q1: If respondents say that freeze-dried vaccines should be stored at -20 ºC this should be recorded as a correct answer, even though current WHO advice is to store these vaccines at +2 to + 8 ºC. If respondents say that freeze-dried vaccines packed with diluents should be stored at -20 ºC, this answer MUST be scored as incorrect. Knowledge of correct storage temperatures is vital. If the respondent gives any incorrect answers, score 0.

2) Q2: It is particularly important that respondents know that freeze-sensitive vaccines must not be exposed to temperatures below 0 ºC. It is not important theat they know the precise freezing temperature of each vaccine.

3) Q7 and Q8: 'Complete' means that there should be no missing record sheets or electronic temperature traces and that the entire 12 month period should be covered for each appliance.

4) Q9: Select a random 7 day period for each appliance (not the same period for each). Check the twice daily temperature records against the corresponding times on the temperature trace. If the record is consistently within 2 ºC of the trace, this is acceptable. If there are significant discrepancies, especially if the temperature record is uniform and the trace is not, interview staff to establish the reasons.

5) Q11, Q12, Q13, Q16: Countries should be encouraged to retain such records for tracing purposes.

C3 Over a period of 12 months, the capacity of cold storage has been sufficient to meet the demand.

Note to assessors: Assessors should use the following documents for information on calculating vaccine storage volumes: 1) *Guidelines on the international packaging and shipping of vaccines* (WHO/V&B/01.05) for data on vaccine volume per dose. 2) *Guideline for improving primary and intermediate vaccine stores* – (WHO/V&B/02.34), Worksheet 1 for the methodology for calculating vaccine storage volumes.

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
3.1	***The store can accommodate peak stock levels for all the vaccines specified in the national immunization schedule, including campaign vaccines where these are normally kept in the primary store.***			
3.1.1	Carry out vaccine volume estimates for all vaccines, diluents and droppers that are stored in the primary store. Accurately establish the maximum volume of vaccines, diluent and droppers that have to be stored at each of the recommended storage temperatures (-15 to -25 ºC, +2 to +8 ºC, and ambient).	**Method:** Review the methodology used and the estimates arrived at. Compare calculated data with peak stock data from the stock records. Record and query any significant discrepancies.		
		Q1: Has a vaccine volume calculation been carried out during the review period and is it in a form which can be assessed (see note 1)? [YES=1, NO=0]		0.00
		Commentary:		
3.1.2	Ensure that the net vaccine capacity of the cold storage available exceeds the calculated maximum vaccine volume.	**Method:** Estimate the capacity of the cold storage available and compare this with the data from 3.1.1. (Note that some programmes record campaign vaccines independently).		
		Q2: Collect the following data to establish whether the capacity of the +2 to + 8 ºC vaccine store has been sufficient throughout the review period.		
		A. Measure the net storage capacity (in litres) of the +2 to +8 ºC store(s). See MQP 3.1.2.		
		B. Using data from stock records, calculate the peak volume (in litres) of +2 to +8 ºC vaccine (note 2 & 3).		
		Note: If peak vaccine volume/net storage capacity is less than or equal to 1, the score is 1, else it is 0.		
		Q3: Collect the following data to establish whether the capacity of the -20 ºC vaccine store has been sufficient throughout the review period.		
		A. Measure the net storage capacity (in litres) of the -20 ºC store(s). See MQP 3.1.2.		
		B. Using data from stock records, calculate the peak volume (in litres) of -20 ºC vaccine (note 2 & 3).		
		Note: If peak vaccine volume/net storage capacity is less than or equal to 1, the score is 1, else it is 0.		
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
3.2	***Where vaccine supplied for campaign use is stored in temporary facilities, these facilities can accommodate peak stock levels.***			
3.2.1	Carry out vaccine volume estimates for all campaign vaccines, diluents and droppers that are stored in the temporary facilities. Accurately establish the maximum volume of vaccines, diluent and droppers that have to be stored at each of the recommended storage temperatures (-15 to -25 ºC, +2 to +8 ºC, and ambient).	**Method:** Review the methodology used and the estimates arrived at. Compare calculated data with peak stock data from the stock records. Record and query any significant discrepancies.		
		Q4: Has a vaccine volume calculation for campaign vaccines been carried out during the review period and is it in a form which can be assessed? [YES=1, NO=0. ***If there are no campaigns, or if campaign vaccine is kept in the main store, enter 'n/a' and omit Q5 and Q6***]		0.00
		Commentary:		
3.2.2	Ensure that the net vaccine capacity of cold storage equipment available exceeds the calculated maximum volume of the campaign vaccines.	**Method:** Estimate the capacity of the cold storage available and compare this with the data from 3.2.1.		
		Q5: Collect the following data to establish whether the capacity of the +2 to +8 ºC campaign vaccine store has been sufficient throughout the review period.		
		A. Measure the net storage capacity (in litres) of the +2 to +8 ºC store(s). See MQP 3.1.2.		
		B. Using data from stock records, calculate the peak volume (in litres) of +2 to +8 ºC vaccine.		
		C. If peak vaccine volume/net storage capacity is less than or equal to 1, score is 1, otherwise it is 0.		
		Q6: Collect the following data to establish whether the capacity of the -20 ºC campaign vaccine store has been sufficient throughout the review period.		
		A. Measure the net storage capacity (in litres) of the -20 ºC store(s). See MQP 3.1.2.		
		B. Using data from stock records, calculate the peak volume (in litres) of -20 ºC vaccine.		
		C. If peak vaccine volume/net storage capacity is less than or equal to 1, score is 1, else it is 0.		
		Commentary:		
			CRITERION 3 SCORE:	**0.00**
			Maximum score:	6.00
			Percentage score:	**0%**

Notes:

1) Q1 and Q4: The calculation must be set out on paper or in a spreadsheet so that the assessor can understand the methodology used
2) Q2 and Q3: Include supplementary immunization vaccines where applicable.
3) Q2 and Q3: Include campaign vaccine in cases where this is kept in the main store.

C4 Over a period of 12 months, the buildings, equipment and transport available to the programme have enabled the cold store to function effectively.

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
4.1	***The store building is suitably sited and is constructed to an adequate standard.***			
4.1.1	Ensure that the site where the store building is located is accessible to staff and transport and is secure.	**Method:** Complete checklist on-site.		
		Q1: Site checklist.		
		A. Is the store building large enough? [YES=1, NO=0].		
		B. Can delivery vehicles easily reach the store? [YES=1, NO=0].		
		C. Is the site secure? [YES=1, NO=0].		0.00
		Commentary:		
4.1.2	Ensure that the store building is of permanent construction, in good structural condition and well maintained, and that it is adequately secured against theft	**Method:** Complete checklist on-site.		
		Q2: Is the building suitable for the climate (insulated and heated in cold climates, shaded and ventilated or air-conditioned in hot climates? [YES=1, NO=0].		0.00
		Q3: Building checklist. (See 6.4.4 for cleanliness & pest control).		
		A. Is the roof free of leaks? [YES=1, NO=0].		
		B. Are the external walls free of severe cracks or other major damage? [YES=1, NO=0].		
		C. Are windows and external doors in good condition and secure (grilles and/or locks)? [YES=1, NO=0].		
		D. Are floors dry and reasonably level? [YES=1, NO=0].		
		E. Is the store free from condensation? [YES=1, NO=0].		
		F. Is the building fitted with an adequate number of working fire extinguishers? [YES=1, NO=0].		
		G. Is the standard of the electrical system satisfactory? [YES=1, NO=0].		
		H. Is the drainage system working (rainwater and foul drainage)? [YES=1, NO=0].		
		J. Is the air-conditioning system working? [YES=1, NO=0. Score 'n/a' in climates where a/c is not required].		
		K. Is the heating system working? [YES=1, NO=0. Score 'n/a' in climates where heating is not required].		
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
4.2	***Accommodation within the store building is satisfactory.***			
4.2.1	Ensure that that the room where the refrigeration equipment is accommodated is large enough. The room should be located close to the packing area and should be adequately ventilated.	**Method:** Complete checklist on-site.		
		Q4:		
		A. Is there sufficient space to service the equipment? [YES=1, NO=0].		
		B. Is the room adequately ventilated? [YES=1, NO=0].		0.00
		Commentary:		
4.2.2	Provide space for packing vaccine for onward dispatch. Ensure that the packing area is large enough and that it is adequately fitted out and equipped.	**Method:** Complete checklist on-site.		
		Q5: Packing area checklist - see MQP Figure 4.2.2.A.		
		A. Is the packing area close to the refrigeration equipment area? [YES=1, NO=0].		
		B. Are the icepack freezers in, or close to the packing area? [YES=1, NO=0].		
		C. Is there sufficient lay out space for conditioning icepacks? [YES=1, NO=0].		
		D. Are the empty cold boxes stored in, or close to the packing area? [YES=1, NO=0].		
		E. Is there sufficient lay out space for packing vaccines into cold boxes? [YES=1, NO=0].		
		F. Is there sufficient space to store packed cold boxes in, or close to the packing area? [YES=1, NO=0].		
		G. Are there hand washing facilities in, or close to the packing area? [YES=1, NO=0].		
		H. Can the temperature of the packing area be maintained between 15 and 25 °C throughout the year? [YES=1, NO=0].		
		J. Is the packing area protected against direct sunlight? [YES=1, NO=0].		0.00
		Commentary:		
4.2.3	Provide an office for the store keeper. This room should be located close to the refrigeration equipment and the packing room and should be adequately equipped.	**Method:** Complete checklist on-site.		
		Q6: Store keeper office checklist - see MQP Figure 4.2.3.A.		
		A. Is the room located so that the store keeper can conveniently supervise vaccine store activities? [YES=1, NO=0].		
		B. Is the room sufficiently large for working and for storing documents (minimum 7.5 m2)? [YES=1, NO=0].		
		C. Is the electrical installation sufficient for the installed equipment (computer, printer, fax machine, etc.)? [YES=1, NO=0].		0.00
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
4.2.4	Provide storage space for diluents, packaging materials, cold boxes and icepacks.	**Method:** Complete checklist on-site.		
		Q7: Storage space checklist.		
		A. Is there adequate storage space for diluents? [YES=1, NO=0].		
		B. Is there adequate storage space for packaging materials? [YES=1, NO=0].		
		C. Is there adequate storage space for cold boxes and unfrozen icepacks? [YES=1, NO=0].		
		D. Is there adequate storage space for consumables (freeze indicators, CCMs, stationary, etc)? [YES=1, NO=0].		0.00
		Commentary:		
4.2.5	Special requirements for refrigerated vehicles, where these are used for vaccine delivery.	**Method:** Complete checklist on-site.		
		Q8. Are refrigerated vehicles used for vaccine deliveries (see MQP 4.2.5 and note 1)? ***[If YES enter 'yes' and continue with A to G. If NO, enter 'no' and go to Q9.]***		
		A. Are all the vehicles and their refrigeration unit in good mechanical condition? [YES=1, NO=0].		
		B. Do the vehicles have current logbooks? [YES=1, NO=0].		
		C. Does the vehicle have an up to date service record? [YES=1, NO=0].		
		D. Are the vehicles fitted with continuous temperature recorders? [YES=1, NO=0].		
		E. Do the refrigeration units maintain a temperature of +2°C to +8°C? [YES=1, NO=0].		
		F. Is there an adequate supply of packing crates for storing vaccine in the vehicles? [YES=1, NO=0].		
		G. Are there sufficient electrical power outlets to operate the refrigeration units when the vehicles are parked? [YES=1, NO=0].		0.00
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
4.3	***The standard of equipment is satisfactory in both permanent and temporary cold stores.***			
4.3.1	Cold rooms and freezer rooms should comply with the following minimum standards:	**Method:** Complete checklist on-site.		
		Q9. Cold room and freezer room checklist - see MQP 4.3.1 (see note 1).		
		A. Are all cold room and freezer room enclosures in good condition at time of inspection? [YES=1, NO=0].		
		B. Are all refrigeration units fully operational at time of inspection? [YES=1, NO=0].		
		C. Do all rooms have continuous temperature recorders? [YES=1, NO=0].		
		D. Do all cold rooms maintain a temperature of +2°C to +8°C? [YES=1, NO=0].		
		E. Do all freezer rooms maintain a temperature of -15°C to -25°C? [YES=1, NO=0].		
		F. Are all cold rooms and all freezer rooms fitted with dual refrigeration units? [YES=1, NO=0].		
		G. Can doors be locked from the outside but freely opened from the inside? [YES=1, NO=0].		
		H. Are all rooms fitted with adequate shelving? [YES=1, NO=0].		
		J. ***Cold climates only.*** Do cold rooms EITHER have low temperature protection OR are they located in a permanently heated room? [YES=1, NO=0. Score 'n/a' if low temperature protection is not required].		
		Commentary:		
4.3.2	Provide adequate protective clothing for staff working in cold rooms and freezer rooms and train staff in safe working practices.	**Method:** Review training records. Complete checklist on-site.		
		Q10: Checklist for working in cold rooms and freezer rooms - see MQP 4.3.2.		
		A. Is warm clothing available for cold store workers? [YES=1, NO=0].		
		B. Have workers received training in safe working in cold stores? [YES=1, NO=0].		0.00
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
4.3.3	Vaccine freezers should comply with WHO specifications and be fitted with a continuous temperature recording device accurate to ±0.5°C.	**Method:** Complete checklist on-site.		
		Q11: Vaccine freezer checklist - see MQP 4.3.3 (See note 1).		
		A. Do all vaccine freezers comply with the WHO specifications that were in force at date of purchase? [YES=1, NO=0].		
		B. Are all vaccine freezers fully operational at time of inspection? [YES=1, NO=0].		
		C. Do all vaccine freezers have continuous temperature recorders? [YES=1, NO=0].		
		D. Are all vaccine freezers provided with thermometers? [YES=1, NO=0].		
		E. Do all vaccine freezers maintain a temperature of -15°C to -25°C? [YES=1, NO=0].		0.00
		Commentary:		
4.3.4	Icepack freezers/chilled water pack coolers should have sufficient capacity to meet the maximum daily demand for icepacks/chilled water packs.	**Method:** Review peak demand calculations. Checklist and inspection.		
		Q12: Icepack freezer/chilled water pack cooler checklist (see MQP 4.3.4):		
		A. Do icepack freezers/coolers have sufficient capacity to meet peak demand? [YES=1, NO=0].		
		B. Do icepack freezers/coolers have sufficient storage capacity to meet peak demand? [YES=1, NO=0].		0.00
		Commentary:		
4.3.5	The use of CFC gases in refrigeration equipment should be phased out in accordance with UNICEF/WHO policy.	**Method:** Inspect refrigeration equipment and identify units that are CFC-free. Establish programme policy on the phasing out of CFC-based equipment.		
		Q13: ***Critical indicator:*** Inspect refrigeration equipment:		
		A. How many refrigeration units are there (dual units count as 2)?		
		B. How many of these are CFC-free?		
		Q14: ***Critical indicator:*** Establish refrigeration equipment replacement policy. If all new equipment is to be CFC-free, score 5. Otherwise score 0.		0.00
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
4.3.6	There should be a standby power supply for the vaccine store, with automatic start-up. Preferably the generator should serve the vaccine store alone.	**Method:** Checklist and inspection. Also establish whether the generator has been out of action at any time due to lack of fuel or lubricant and note this in the commentary.		
		Q15: Is there a standby generator (automatic or manual start-up)? [YES=1, NO=0] ***If YES, complete Q16, otherwise go to Q17.***		1.00
		Q16: Standby generator checklist (see MQP 4.3.6)?		
		A. Is the generator in working order? [YES=1, NO=0].		
		B. Can the generator start all the connected equipment in the vaccine store (see note 2)? [YES=1, NO=0].		
		C. Is the fuel tank large enough? [YES=1, NO=0].		
		D. Are there adequate reserve supplies of fuel? [YES=1, NO=0].		
		E. Is the generator in a secure compound? [YES=1, NO=0].		0.00
		Commentary:		
4.3.7	Provide voltage regulators for all refrigeration equipment wherever voltage fluctuations exceed +/- 15% of rated voltage (or the refrigeration equipment manufacturer's voltage tolerance, whichever is lower)	**Method:** By enquiry, establish the maximum voltage fluctuations affecting the store supply.		
		Q17: Is the voltage fluctuation sufficiently severe to require voltage regulation equipment? ***[If YES, enter 'yes' and complete Q18, otherwise enter 'no' and go to Q19 - any responses to Q18 will not be counted].***		
		Q18: Voltage regulator checklist.		
		A. How many cold rooms are there?		
		B. How many have functioning voltage regulators?		
		C. How many freezer rooms are there?		
		D. How many have functioning voltage regulators?		
		E. How many vaccine freezers are there?		
		F. How many have functioning voltage regulators?		0.00
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
4.3.8	Temperature alarms should be fitted to all refrigeration equipment used to store vaccine.	**Method:** Review record of alarm events. Review standing orders. Checklist and inspection.		
		Q19: Temperature alarm equipment checklist.		
		A. How many cold rooms are there?		
		B. How many have functioning alarm systems?		
		C. How many freezer rooms are there?		
		D. How many have functioning alarm systems?		
		E. How many vaccine freezers are there?		
		F. How many have functioning alarm systems?		
		Commentary:		
4.3.9	National telecommunications links should be sufficient to manage vaccine clearance and distribution.	**Method:** Inquiry and inspection.		
		Q20: Are telecommunications links adequate? [YES=1, NO=0].		0.00
		Commentary:		
4.3.10	Where a computerized stock control system is used, the software and computer equipment should be suitable for the task and staff should be adequately trained.	**Method:** Inquiry and inspection.		
		Q21: Is a computerized stock control system in use? ***[If YES, enter 'yes' and complete Q22, otherwise enter 'no' and go to Q23].***		
		Q22: Is the computer equipment and software adequate for its purpose and in working order? [YES=1, NO=0].		0.00
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
4.4	***Satisfactory arrangements are in place for moving vaccine from primary storage to intermediate level storage, including arrangements for the maintenance of correct temperatures during transport.***			
4.4.1	Provide reliable vehicles, with sufficient carrying capacity, whenever vaccines need to be distributed.	**Method:** In cases where vaccine is **collected** by the intermediate stores, vehicle inspection does not form part of the assessment exercise. In **all other** cases transport is assumed to be the responsibility of the primary store, either in the form of a directly operated or a contracted-out transport service. In all such cases, inspect vehicles, logbooks, service records and assess driver training (see para 1.5.1)		
		Q23: Is transport the responsibility of the primary store? ***[If YES, enter 'yes' and complete Q24, 24 and 26, otherwise enter 'no' and go to Q27].***		
		Q24: Vehicle checklist:		
		A. Are the vehicle(s) in good mechanical condition? [YES=1, NO=0].		
		B. Does each vehicle have a current logbook? [YES=1, NO=0].		
		C. Does each vehicle have an up to date service record? [YES=1, NO=0].		0.00
		Commentary:		
4.4.2	Train drivers how to use vehicles responsibly.	**Method:** Inspect driver training records. Interview drivers.		
		Q25: Driver training checklist: ***Ignore this question if you have answered NO to Q23.***		
		A. Have drivers received training in safe driving techniques? [YES=1, NO=0]		
		B. Do drivers know how to look after vaccine during transport? [YES=1, NO=0]		
		C. Are drivers knowledgeable about the routes they travel? [YES=1, NO=0]		0.00
		Commentary:		
4.4.3	Supply fuel and lubricant for all required journeys.	**Method:** Establish whether any deliveries have been delayed due to lack of fuel during the review period? N/a for collection.		
		Q26: Fuel checklist: ***Ignore this question if you have answered NO to Q23.***		
		A. During the review period, was sufficient fuel available to allow all deliveries to be completed on time? [YES=1, NO=0].		0.00
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
4.4.4	Transport vaccine in cold boxes which have a cold-life (or in cold climates, a warm-life) sufficient for the longest expected journey.	**Method:** Establish whether effective training has been carried out. Interview selected staff to establish their understanding of icepack conditioning, use of cool packs or warm packs (as relevant) and general **tr**ansport procedures.		
		Q27: Do stores staff know how to condition icepacks and/or use chilled water packs and how know how to pack transport boxes?		
		A. Icepack conditioning/chilled water pack cooling in accordance with WHO guidelines [YES=2, NO=0]		0.00
		B. Packing in accordance with WHO guidelines [YES=1, NO=0]		0.00
		Commentary:		
4.4.5	Where refrigerated vehicles are used to transport vaccine, teach drivers how to use the equipment.	**Method:** Establish whether effective training has been carried out. Interview selected staff to establish understanding of vaccine packing and transport procedures.		
		Q28: Do drivers know how to operate refrigerated vehicles? [YES=1, NO=0. ***Enter 'n/a' if refrigerated vehicles are not used***].		0.00
		Commentary:		
		CRITERION 4 SCORE:		**0.00**
		Maximum score:		35.00
		Percentage score:		**0%**

Notes:

1) Q8, Q9, Q11: Ignore any equipment which is out-of-service for a legitimate reason - for example because it is being serviced or repaired. Check that any vaccine that was stored in the out-of-service equipment is being kept under safe conditions.

2) Q16: The starting load for a refrigeration compressor is much higher than the running load. If there is a power failure, the generator must be able to cope with the combined starting load of all connected refrigeration units.

C5 Over a period of 12 months, all buildings, equipment and transport have been correctly maintained.

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
5.1	***Planned preventive maintenance to buildings, equipment and transport is carried out.***			
5.1.1	**Buildings:** Set up a planned preventive maintenance regime and provide evidence that this plan is being followed.	**Method:** Review the building maintenance plan. Inspect maintenance records. Compare with evidence from physical inspection recorded in 4.1.2 and evidence concerning the maintenance budget recorded in 10.2.3.		
		Q1. Assess building maintenance over the review period - see MQP 5.1.1 (commentary only):		
		Commentary:		
5.1.2	**Equipment:** Set up a planned preventive maintenance, overhaul and replacement plan and provide evidence that this plan is being followed.	**Method:** Review the equipment maintenance plan. Inspect maintenance records. Inspect any maintenance contracts that are in place. Compare with evidence from physical inspection recorded in 4.3 and evidence concerning the maintenance budget recorded in 10.2.4. Good indicators of poor routine maintenance are noisy refrigeration units, damaged door seals, corroded panels, missing light bulbs, etc.		
		Q2. ***Critical indicator:*** Assess equipment maintenance over the review period - see MQP 5.1.2:		
		A. Was there an itemised preventive maintenance plan? [YES=1, NO=0].		
		B. Was there an itemised equipment replacement plan? [YES=1, NO=0].		
		C. Was there an effective financial control and costing system in place? [YES=1, NO=0].		
		D. Was there a plan of work to execute the maintenance plan? [YES=1, NO=0].		
		E. Was there an effective reporting system? [YES=1, NO=0].		
		F. Was the maintenance work, described in the plan, carried out satisfactorily? [Score 0 to 4].		
		G. Was equipment replaced as described in the plan? [Score 0 to 4].		0.00
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
5.1.3	**Transport:** Set up a planned preventive maintenance, overhaul and replacement plan and provide evidence that this plan is being followed (note 1).	**Method:** Review the transport maintenance plan. Inspect maintenance records. Inspect any maintenance contracts that are in place. Compare with evidence from physical inspection recorded in 4.4 and evidence concerning the maintenance budget recorded in 10.2.5. ***If you answered 'no' to C4:Q23 then vaccines are collected. A message will appear here and you should omit Q3, Q6 and Q9.***		
		Q3. Assess vehicle maintenance over the review period - see MQP 5.1.3:		
		A. Was there an itemised preventive maintenance plan? [YES=1, NO=0].		
		B. Was there an itemised vehicle replacement plan? [YES=1, NO=0].		
		C. Was there an effective financial control and costing system in place? [YES=1, NO=0].		
		D. Was there an effective reporting system? [YES=1, NO=0].		
		E. Was the maintenance work, described in the plan, carried out satisfactorily? [Score 0 to 4].		
		F. Were vehicles replaced as described in the plan? [Score 0 to 4].		0.00
		Commentary:		
5.2	***Emergency repairs are conducted in a timely manner and are reported.***			
5.2.1	**Buildings:** ensure emergency repairs to buildings are carried out promptly to avoid risk of damage to vaccine.	**Method:** Maintenance records. Physical inspection and enquiry. Good indicators of poor emergency maintenance are missing light bulbs, broken windows, blocked drains etc.		
		Q4. Does the condition of the buildings indicate that emergency repairs and replacements have been carried out effectively? [YES=1, NO=0].		0.00
		Commentary:		
5.2.2	**Equipment:** ensure emergency repairs to equipment are carried out promptly to prevent risk of damage to vaccine. Where this has not been possible, provide evidence that the contingency plan has been implemented effectively, and in a timely manner.	**Method:** Maintenance records. Physical inspection and enquiry. Good indicators of poor emergency maintenance are broken refrigeration units and other non-operational equipment.		
		Q5. ***Critical indicator:*** During the review period did any cold room or freezer fail to the extent that vaccine was damaged? [NO= 5, YES=0]		0.00
		Commentary:		

Ref	REQUIREMENTS		ASSESSMENT METHOD	RESULTS	SCORE
5.2.3	**Transport:** ensure emergency repairs to vehicles are carried out promptly to avoid risk of damage to vaccine in transit and/or to ensure the vaccine delivery schedule is unaffected. Where this has not been possible, provide evidence that the contingency plan has been implemented effectively, and in a timely manner.		**Method:** Maintenance records. Physical inspection and enquiry.		
		Q6.	***Critical indicator:*** During the review period did any vehicle fail to the extent that vaccine was damaged (note 2)? [NO= 5, YES=0]		0.00
		Commentary:			
5.3	***Adequate supplies of spare parts and consumables are available.***				
5.3.1	**Buildings:** maintain sufficient supplies of spare parts and maintenance consumables to ensure that the building operates effectively.		**Method:** Review stock records. Physical inspection and enquiry.		
		Q7.	Is there an adequate stock of spare parts and maintenance consumables? Commentary only.		
		Commentary:			
5.3.2	**Equipment:** maintain sufficient supplies of spare parts and consumables to ensure that equipment operates effectively.		**Method:** Review stock and maintenance records. Physical inspection and enquiry.		
		Q8.	During the review period, did a shortage of spare parts or consumables cause any cold room freezer room or freezer to be removed from service for longer than 7 days? [YES=0, NO=1].		0.00
		Commentary:			
5.3.3	**Transport:** maintain sufficient supplies of spare parts and consumables to ensure that transport operates effectively.		**Method:** Review stock and maintenance records. Physical inspection and enquiry. If vaccines are collected, n/a will appear here.		
		Q9.	During the review period, did a shortage of consumables (tyres, etc) cause any vehicle to be removed from service for longer than 7 days? [YES=0, NO=1].		0.00
		Commentary:			
			CRITERION 5 SCORE:		**0.00**
			Maximum score:		19.00
			Percentage score:		**0%**

Notes:

1) 5.1.3: In this context, 'planned preventive maintenance' (PPM) is as defined in the manufacturer's service manual. Both the need for and the timing of PPM can be foreseen. 'Overhaul' means the dismantling or replacement of major components, such as clutch linings, engines, transmissions, etc. The timing may vary between similar vehicles, but the need can be foreseen. 'Replacement policy' means the disposal of the vehicle at a rationally established point in its life.

2) Q6: Ignore losses arising from traffic accidents for which the driver was not directly responsible.

C6 Over a period of 12 months, stock management has been effective.

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
6.1	***Standardized recording and reporting of all stock transactions is carried out. Preferably this is computerized at the primary level.***			
6.1.1	**Arrival.** Accurately record incoming vaccines, diluents and droppers, and other consumables.	**Method:** Inspect stock records over the review period.		

Q1: ***Critical indicator:*** For freeze-dried vaccines, during the review period, did the stock recording system record:

A:	Vaccine & diluent quantity (in doses)? [YES=1, NO=0].	
B:	Vaccine & diluent type? [YES=1, NO=0].	
C:	Vaccine & diluent manufacturer? [YES=1, NO=0].	
D:	Vaccine & diluent vial size? [YES=1, NO=0].	
E:	Vaccine & diluent batch/lot number (note 1)? [YES=1, NO=0].	
F:	Vaccine & diluent expiry dates (note 1)? [YES=1, NO=0].	
G:	Bin location? [YES=1, NO=0].	
H:	VVM status (where applicable)? [YES=1, NO=0].	0.00

Commentary:

Q2: ***Critical indicator:*** For liquid vaccines, during the review period, did the stock recording system record:

A:	Vaccine quantity (in doses)? [YES=1, NO=0].	
B:	Vaccine type? [YES=1, NO=0].	
C:	Vaccine manufacturer? [YES=1, NO=0].	
D:	Vaccine vial size? [YES=1, NO=0].	
E:	Vaccine batch/lot number (note 1)? [YES=1, NO=0].	
F:	Vaccine expiry dates (note 1)? [YES=1, NO=0].	
G:	Bin location? [YES=1, NO=0].	
H:	VVM status (where applicable)? [YES=1, NO=0].	
J:	Freeze indicator status (where applicable)? [YES=1, NO=0].	0.00

Commentary:

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
6.1.2	**Requisitions.** Operate an effective system for receiving and checking requisitions.	**Method**: Establish whether a formal requisition system exists. Inspect a representative sample of requisition forms. If no requisition system, is there a method for adjusting quantities issued to real need.		
		Q3: Assess system performance during the review period:		
		A: Was a formal requisition system in place? [YES=1, NO=0].		
		B: Does the requisition include a 'remaining stock report' in the receiving store? [YES=1, NO=0].		
		C: If no requisition system, is a method being used to adjust quantities according to remaining stock? [YES=1, NO=0].		0
		Commentary:		
6.1.3	**Dispatch:** Establish a pre-delivery or pre-collection notification system.	**Method**: Establish whether a formal pre-delivery or pre-collection notification system exists. Inspect a representative sample of notification forms. (note: some systems may have an annual plan. In such cases only variations from the plan need notification)		
		Q4: Assess notification system performance during the review period:		
		A: Was a formal notification system in place? [YES=1, NO=0].		
		B: Were notifications actually issued? [YES=1, NO=0].		
		C: Was the notification period generally adequate? [YES=1, NO=0].		0.00
		Commentary:		
6.1.4	**Dispatch.** Issue vaccines, diluents and other date-limited products in EEFO order. If VVM status indicates that some vaccine vials should be used ahead of its correct EEFO order, this may be done, but the reason for doing so should be recorded.	**Method:** Inspect stock records. Query any examples of non-EEFO vaccine issues and/or inspect relevant records covering this action. Check whether diluents were issued correctly.		
		Q5: Do stock records for the review period indicate adherence to EEFO principles (note 1)? [YES=1, NO=0].		0.00
		Q6: Assess the response to VVM and freeze indicator changes during the review period:		
		A. Are VVM and freeze indicator changes recorded? [YES=1, NO=0].		
		B. Are vials with VVM changes issued ahead of their EEFO sequence (note 3)? [YES=1, NO=0. Score 1 if no VVM changes have occurred].		
		C. If freeze indicator changes are recorded, note in the commentary what action was taken. [If the response was correct score 1, otherwise score 0. If no freeze indicator changes occurred score 'n/a'].		0.00
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
6.1.5	**Dispatch.** When vaccines and consumables leave the store, verify the information in the stock record system for all items that are issued. Record any change in VVM status in the stock record system and transfer this information accurately to the vaccine delivery/arrival form.	**Method:** Compare stock records with a representative sample of completed delivery/arrival forms.		
		Q7: Does the primary store have a completed delivery section of the delivery/arrival form for every delivery which took place during the review period (note 4)? [YES=1, NO=0].		0.00
		Q8: Do the vaccine quantities recorded on the delivery section of the delivery/arrival form consistently match the relevant entries in the stock records? [YES=1, NO=0].		0.00
		Commentary:		
6.1.6	**Arrival at intermediate store.** When vaccines and consumables arrive at the intermediate store, check the delivery/arrival form, report any discrepancies and report all indicator changes.	**Method:** Establish whether the primary store retains completed delivery/arrival forms from the intermediate stores. If it does, check a representative sample.		
		Q9: Does the primary store have a completed arrival section of the delivery/arrival form for every delivery which took place during the review period (note 5)? [YES=1, NO=0].		0.00
		Q10: Does a representative sample of these completed forms indicate that arrival checks were carried out correctly? [YES=1, NO=0].		0.00
		Commentary:		
6.1.7	**Disposal.** Safely dispose of damaged or expired stock in accordance with standing orders.	**Method:** Review disposal procedures and records. Inspect disposal facilities. Refer to 2.1.5 and 2.1.6 for accounting assessment.		
		Q11: Are damaged/expired vaccines and diluents clearly labelled and packaged and stored out of the cold chain (note 6)? [YES=1, NO=0].		0.00
		Q12: During the review period, were damaged/expired vaccines clearly identified in the stock recording system? [YES=1, NO=0].		0.00
		Q13: Are disposal facilities and procedures in accordance with WHO and/or national norms? [YES=1, NO=0].		0.00
		Commentary:		
6.1.8	Back up all computer records at least once a week.	**Method:** Review backup procedures.		
		Q14: Are computer records backed up at least once a week? [YES=1, NO=0. Score 'n/a' if a computer-based system is not used].		0.00
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
6.2	***Stocks have been maintained between the safety stock level and the maximum stock level for each vaccine and for other consumables.***			
6.2.1	Establish a maximum stock level and a safety (reserve) stock level for each vaccine and for each consumable. Ensure that it is possible to store the maximum anticipated stock within the facility.	**Method:** Review the purchasing method adopted and the related delivery frequency. Review the target safety stock and maximum stock levels and compare with evidence from the VARs and stock records.		
		Q15: Assess safety stock policy during the review period:		
		A: Were maximum stock levels appropriate to vaccine expiry dates (note 7) ? [YES=1, NO=0].		
		B: Was a safety stock level set for each vaccine? [YES=1, NO=0].		
		C: Was the level appropriate to the delivery lead time? [YES=1, NO=0].		0.00
		Commentary:		
6.2.2	When orders for new vaccine stocks and consumables are placed, allow sufficient lead-time so as to ensure that each item arrives before the safety stock level for that item is breached.	**Method:** Review stock records and vaccine orders to establish whether adequate lead times have been allowed. Assess the incidence of stockouts, failed deliveries and breached safety stocks during the review period for all vaccines and diluents:		
		Q16: During the review period, did the programme for placing orders take adequate account of lead-times? [YES=1, NO=0].		0.00
		Q17: ***Critical indicator:*** Assess the incidence of stockouts and related events during the review period arising as a result of programme failure (note 8):		
		A. No stockouts? [YES=2, NO=0]:		
		B. No instances where low stock levels affected deliveries to intermediate stores? [YES=2, NO=0]:		
		C. No instances where safety stock levels were breached? [YES=1, NO=0]:		0.00
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
6.3	***Periodic physical inventories have been conducted.***			
6.3.1	Carry out a physical inventory of vaccine, diluent and dropper stocks must be carried out at least once every three months.	**Method:** Check whether physical counts have been carried out and recorded. Ignore counts that are reported, but not properly recorded. Carry out a sample physical count of the vaccine stock to establish whether stock records are accurate. Choose a freeze-dried vaccine, preferably one with a separately packed diluent.		
		Q18: How many recorded physical counts of vaccine stocks were carried out during the review period?		0.00
		Q19: ***Critical indicator:*** Choose a sample vaccine/diluent combination. Enter it in the box below (note 9 & 10):		
		A. Carry out a physical count of the sample vaccine. Enter number of doses counted:		
		B. Check stock records for sample vaccine. Enter number of doses recorded as currently in stock:		
		C. Carry out a physical count of the sample diluent. Enter number of doses counted:		
		D. Check stock records for sample diluent. Enter number of doses recorded as currently in stock: [Score 5 only if count and records match exactly AND vaccine and diluent quantities also match exactly. Use your judgement to adjust the score between 4 and 0 for any mismatch].		0.00
		Commentary:		
6.3.2	Carry out a physical inventory of other consumables (AD syringes, safety boxes, consumables, spare parts, etc.) at least once every three months.	**Method:** Check whether physical counts have been carried out and recorded. Ignore counts that are reported, but not properly recorded. Carry out a sample physical count of the consumables stock to establish whether stock records are accurate.		
		Q20: How many recorded physical counts of consumables stock were carried out during the review period? ***(If store does not manage dry goods, enter 'n/a' and go to Q22).***		0.00
		Q21: Choose a sample consumable. Enter it in box below:		
		A. Carry out a physical count of the sample consumable. Enter number of items counted:		
		B. Check stock records for sample consumable. Enter number of items recorded as currently in stock:		
		C. [Score 5 only if count and records match exactly. Use your judgement to adjust the score between 4 and 0 for any mismatch].		0.00
		Commentary:		
6.4	***Good warehousing practices are in place.***			
6.4.1	**Stock security:** keep all vaccines and consumables under secure conditions.	**Method:** Check that valuable vaccines and valuable consumables are kept under lock and key.		
		Q22: Is the stock secure? [YES=1, NO=0]		0.00
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
6.4.2	**Data security:** keep all records secure.	**Method:** Check whether records are kept in locked filing cabinets and whether the room containing the records is locked when unoccupied.		
		Q23: Are the records secure? [YES=1, NO=0]		0.00
		Commentary:		
6.4.3	**Storage:** store all vaccines, diluents and droppers and other consumables in an orderly fashion.	**Method:** Note whether items are systematically laid out, whether EEFO discipline is being observed (where appropriate), that shelves are labelled and that staff can find specific items easily.		
		Q24: Is stock laid out in an orderly fashion? [YES=1, NO=0]		0.00
		Commentary:		
6.4.4	**Cleanliness:** keep the vaccine store clean and free of pests.	**Method:** Establish how frequently the store is cleaned. Look for evidence of accumulated rubbish and general untidiness and for rat and bat droppings, cockroaches, ants and other insects.		
		Q25: Is the vaccine store clean and pest-free? [YES=1, NO=0]		0.00
		Commentary:		
6.4.5	**Supervision:** ensure that all staff are effectively supervised.	**Method:** ***Refer to C10: 10.4.2 - Q6***		
		Commentary only:		
			CRITERION 6 SCORE:	**0.00**
			Maximum score:	41.00
			Percentage score:	**0%**

Notes:

1) Q1: All diluents must have lot numbers and expiry dates. The assessors should check this. If this information is missing the team should notify Dr Nora Dellepiane at WHO Geneva (dellepianen@who.int).
2) Q5: Query any non-EEFO issues. If the reason for issue in non-EEFO order is legitimate the answer to this question can still be 1.
3) Q6: Judgement and observation are required. VVM changes may have occurred, but not have been noticed or recorded.
4) Q7: Use judgement here. If the review period has just ended, VARs for recent deliveries may not yet have been filed. However, there are unlikely to be any other legitimate reasons for missing delivery sections.
5) Q9: Use judgement. If the review period has just ended, VARs for recent deliveries may not yet have been received by the primary store. There may be other legitimate reasons for missing forms. Equally, suspiciously 'correct' forms may conceal lax practices.
6) Q11: If vaccine has to be discarded, any associated diluent should also be discarded. Failure to do this can lead to a stockpile of orphaned diluent.
7) Q15: Assess whether the store held excessive stock during the review period. Whilst no vaccine may actually have expired in the primary store, excessive stock primary level exposes vaccine the risk because it cannot be distributed to the service point level before it expires.
8) Q17: Do *not* include stockouts arising as a result of late delivery by the vaccine supplier *unless* this late delivery was a consequence of a failure by the programme to order vaccines in good time.
9) Q19: Use judgement. There may be legitimate reasons why the count and the record do not tally - e.g. an order may just have been filled and the records may not have been updated. Equally, accurate records may conceal underlying problems. However there is unlikely to be a legitimate reason why vaccine and diluent quantities do not match closely.
10) Q19: Choose a freeze-dried vaccine/diluent combination for this exercise. By doing this it is possible to assess whether diluents are being controlled correctly.

C7 Over a period of 12 months, deliveries of vaccine to the next level have been timely and sufficient.

Note to assessors: Because there are relatively few questions listed under criteria 7 and 8, the radar chart combines their scores.

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
7.1	***Distribution reports indicate compliance with the planned delivery schedule.***			
7.1.1	Maintain a programme for the distribution of vaccine from the primary to the intermediate stores. The programme should be flexible enough to accommodate variations in demand from service points.	**Method:** Review the delivery programme and the data on which this is based. Where discrepancies exist, undertake enquiries into coverage, wastage rates and related issues.		
		Q1: During the review period, did the primary store send a programme to the intermediate stores setting out dates for the delivery and/or collection of vaccines (note 1)? [YES=1, ***If there is no effective programme, score 0 and go to Q3***]		0.00
		Q2: Assess the reliability of actual delivery/collection dates against the programme (note 1 and note 2).		
		A. Record number of deliveries/collections (to all intermediate stores) scheduled during review period:		
		B. Record the number of deliveries/collections made during the review period.		
		C. Percentage of planned deliveries/collections actually made: (If between 90% and 110% score = 1, OR else score = 0)		n/a
		Commentary:		
		Q3: Assess the timeliness of a sample of actual deliveries/collections. [Score on a scale of 0-4, where 0 indicates that deliveries/collections were consistently unreliable and 4 indicates that they were consistently reliable].		0
		Commentary:		
		Q4: Where scheduled deliveries were made by the primary store, was transport reliably provided. [YES=1, NO=0. Score n/a if primary store does not make deliveries.]		0
		Commentary:		
7.1.2	Maintain an effective reporting system which monitors actual vaccine distributions and compares these with anticipated distributions.	**Method:** Review the reporting system.		
		Q5: During the review period, was there a reporting system which monitored actual vaccine distributions and compared these with anticipated distributions? [YES=1, NO=0]		0.00
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
7.2	***A system for managing short shipments is in place.***			
7.2.1	Maintain an effective system for managing short shipments to intermediate stores.	**Method:** Review procedures for managing short shipments. Review records to establish whether such procedures were followed effectively.		
		Q6: If there were short shipments during the review period, were they followed up and corrected? [Score 4 if there were no short shipments. Otherwise evaluate the effectiveness with which short shipments were managed and score on a scale of 0-4].		0
		Commentary:		
			CRITERION 7 SCORE:	**0.00**
			Maximum score:	6.00
			Percentage score:	**0%**

Notes:

1) Q1 and Q2: These questions are intended to establish whether the programme has an effective vaccine distribution plan.

2) Q2: What constitutes an acceptable degree of reliability will depend to some extent upon local conditions. For example if roads are regularly flooded or washed away in the rainy season, then the delivery schedule should be planned to take account of this eventuality. On the other hand, delays due to the unexpected - say an earthquake or civil disorder - should not effect the result.

3) Q3: The fact that a requisition is fully filled is no guarantee that the requisition itself is 'correct'. It may be too high, reflecting excessive wastage at the periphery, or it may be too low, reflecting poor coverage. However, this is a matter to be addressed in a programme review, NOT by the CSCI assessment. Nevertheless the assessor may wish to note his/her observations, particularly where it is evident that the primary store is making unilateral adjustments to requisitions. The commentary should include an explanation for any significant mismatches between planned and actual deliveries.

C8 Over a period of 12 months, no damage has occurred to the vaccine during distribution.

Note to assessors: Despite the wording of this criterion, there are a number of ways in which vaccine may be damaged or lost during distribution which are not the fault of the distribution system. For example, there could have been a serious traffic accident involving the delivery vehicle, for which the driver is not responsible. To take account of such events, question **Q5** allows a percentage loss without prejudicing the overall score. However, where such losses have occurred, it is essential that the assessors inquire as to the cause(s) and record this in the commentary. If the main reason for the loss is a system failure then this should be stated and may be used as justification to downgrade the score. Because there are relatively few questions listed under criteria 7 and 8, the radar chart combines their scores.

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
8.1	***Freeze indicators are used in all deliveries.***			
8.1.1	Insert a Freeze indicator in every vaccine shipment from the primary store to the intermediate stores.	**Method:** Review a one-month sample of delivery/arrival forms received from intermediate stores.		
		Q1: Were freeze indicators packed with deliveries of freeze-sensitive vaccines during the review period? [Score on a scale of 0-4 where 4 indicates that freeze indicators were used on all deliveries and 0 indicates that they were never used]		0.00
		Q2: During the review period, was freeze indicator status recorded on all VARs returned by the intermediate stores? [YES=1, NO=0]		0.00
		Commentary:		
8.2	***In case of failure, damage has been reported and vaccine has been replaced on time.***			
8.2.1	If any indicators show exposure to adverse temperatures, check the vaccine and notify the primary store.	**Method:** Review a one month sample of the delivery/arrival forms received from intermediate stores.		
		Q3: During the review period, was VVM status recorded on all delivery/arrival forms returned by the intermediate stores? [YES=1, NO=0. ***Score 'n/a' if there are no VVMs on the supplied vaccines***].		0.00
		Q4: Is there evidence that any suspected frozen vaccine was shake tested ? [YES=1, NO=0].		0.00
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
8.2.2	Replace damaged vaccine as soon as possible.	**Method:** Inspect stock records, disposal reports and other evidence that damaged vaccine has been replaced in a timely manner.		
		Q5: ***Critical indicator.*** During the review period, was any vaccine lost due to incorrect transport conditions? [***If no vaccine was lost, score 1, otherwise score 0 and then collect the following information to establish the percentage of doses that were lost.***] .		0.00
		A. Record number of doses of all vaccines issued during the review period - see 2.1.2 Q5.		
		B. Record number of doses of all vaccines discarded during the review period because of incorrect transport.		
	PERCENTAGE LOSS CALCULATION	C. Percentage loss calculation from data entered in A and B		0.00
		D. Was the damaged vaccine replaced within a reasonable period of notification to the primary store? [YES=1, NO=0] .		0.00
		Commentary:		
			CRITERION 8 SCORE:	**0.00**
			Maximum score:	9.00
			Percentage score:	**0%**

C9 Over a period of 12 months, the facility has followed standard operating procedures.

Note to assessors: The requirements in this section cannot easily be scored numerically. Consequently the 'SCORE' column has been omitted. Assessors should answer the various questions on the basis indicated. Where a score on a scale of 0-4 is requested, 0 is wholly unsatisfactory or absent, and 4 is excellent. Each answer should be supplemented by a thorough commentary. It is intended that these commentaries will form the principal basis for the inspection team's assessment of this section.

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
9.1	***Standard operating procedures are in place.***			
9.1.1	Standard operating procedures should be presented in a form which can be easily understood by the cadre of staff who carry out the procedures.	**Method**: Review the document and compare with the advice given in the *Model Quality Plan.*		
		Q1: Is a *Standard Operating Procedures* (SOP) manual in existence? [YES/NO]. ***If the answer to Q 1 is YES continue with the following questions. If the answer is NO complete the commentary below and go to Q6.***		
		Commentary:		
		Q2: Is the SOP manual general in conformity with the advice given in the *Model Quality Plan?* [Score on a scale of 0-4 and elaborate in the commentary].		
		Q3: Is there an effective mechanism for keeping the SOP manual up-to-date? [Score on a scale of 0-4].		
		Commentary:		
9.2	***Every cold store has a copy of the standard operating procedures, and records are kept as evidence of compliance.***			
9.2.1	Standard operating procedures should be supplied to every cold store in a form which ensures that procedures are updated as instructed.	**Method:** Establish whether SOP manuals have been physically issued, and whether they are being maintained.		
		Q4: Does the primary store have a copy of the SOP manual? [YES/NO].		
		Q5: Does every intermediate store have a copy of the SOP manual? [YES/NO].		
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
9.3	***Staff are trained in the application of the standard operating procedures.***			
9.3.1	Staff should understand the routine day-to-day application of standard operating procedures, including the importance of in-service staff training.	**Method:** Question primary store staff.		
		Q6: In the assessor's opinion, how good is the storekeeper's knowledge and understanding of the SOPs? See note 1. [Score on a scale of 0-4 and elaborate in the commentary].		
		Commentary:		
9.3.2	Suitable training aids should be used, which are adapted to the educational level of each cadre of staff.	**Method:** Review training curriculum and materials and establish whether staff understand this material.		
		Q7: Are training materials for teaching primary store staff adequate (note 2)? [Score on a scale of 0-4].		
		Q8: Are these training materials generally compatible with the advice given in the *Model Quality Pla*n? [answer YES/NO and elaborate in the commentary].		
		Commentary:		

Notes:

1) Q6: This is not an easy question to answer. The assessor will need to spend time with the storekeeper, observe his/her operating methods, and ask questions which reveal her/his knowledge.

2) Q7: If training materials exist, but there is no SOP document, assess the training materials in their own right. Training materials should cover all the key issues outlined in the *Model Quality Plan*.

C10 Over a period of 12 months, human and financial resources have been sufficient.

Note to assessors: The sub-criteria in this section cannot easily be scored numerically. Consequently the 'SCORE' column has been omitted. Assessors should answer the various questions on the basis indicated. Where a score on a scale of 0-4 is requested, 0 is wholly unsatisfactory or absent, and 4 is excellent. Each answer should be supplemented by a thorough commentary. It is intended that these commentaries will form the principal basis for the inspection team's assessment of this section. The assumption throughout is that the assessment of Criterion 10 will be carried out after completing Criteria 1 to 9. Consequently the assessors should be in a position to evaluate the cold chain development plan and the adequacy of funding and staffing arrangements in the light of earlier findings.

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
10.1	***An annual work plan exists***			
10.1.1	An annual work plan is in existence, which includes the human and financial resource needs of the primary store.	**Method:** Assess the work plan and compare it with evaluated needs. Review any immunization assessment plans carried out within the past three years.		
		Q1: Does a work plan/budget exist for the review period? [YES/NO]		
		Q2: In the light of the completed assessment of Criteria 1 to 9, did the plan adequately cover the following topics:		
		A. Cold chain equipment? [Score on a scale of 0-4].		
		B. Vehicles? [Score on a scale of 0-4].		
		C. Maintenance issues? [Score on a scale of 0-4].		
		D. Staff resources? [Score on a scale of 0-4].		
		E. Staff training? [Score on a scale of 0-4].		
		Commentary:		
		Q3: Has an immunization assessment been carried out within the past three years? [YES/NO]		
		A. If so, did the plan contain recommendations for the primary store? [YES/NO]		
		B. If yes, have these recommendations been implemented? [YES/NO]		
		Commentary:		
10.2	***Secured recurrent funding, or secured donor funding, is sufficient.***	**Method:** Obtain budget figures. In discussion with the EPI manager, assess their adequacy when compared with observed needs.		
10.2.1	Secured recurrent funding should be sufficient to purchase vaccine, injection equipment and related consumables.			
10.2.2	Secured recurrent funding should be sufficient to pay and to train staff.			
10.2.3	Secured recurrent funding should be sufficient to maintain equipment.			

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
10.2.4	Secured recurrent funding should be sufficient to maintain vehicles.			
		Q3: Under each of the following headings, was secured funding, from whatever source, adequate to maintain the programme throughout the review period?		
		A. Purchase of vaccines, injection equipment, waste management equipment and temperature monitoring consumables (10.2.1)? [YES/NO].		
		B. Staff salaries (10.2.2)? [YES/NO].		
		C. Staff training (10.2.2)? [YES/NO].		
		D. Cold chain equipment maintenance and running costs (10.2.4)? [YES/NO].		
		E. Vehicle maintenance and running costs (10.2.5)? [YES/NO].		
		Commentary:		
10.3	***Capital funding, or promised donor funding, is sufficient for the next 12 months.***	**Method:** Obtain budget figures. In discussion with the EPI manager, assess their adequacy when compared with observed needs.		
10.3.1	Capital funding should be sufficient to carry out planned equipment replacement.			
10.3.2	Capital funding should be sufficient to carry out planned vehicle replacement.			
		Q4: Under each of the following headings, was secured funding, from whatever source, adequate to carry out the planned renewal programme throughout the review period?		
		A. Planned cold chain equipment replacement? [YES/NO. If no plan score NO].		
		B. Planned vehicle replacement? [YES/NO. If no plan score NO].		
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
10.4	***Sufficient qualified staff are employed to operate the store effectively.***			
10.4.1	There should be the correct number of staff to fill all the posts in the store establishment.	**Method:** Check the store establishment plan, compare it with the staff roster and assess the adequacy of staffing levels.		
		Q5: Were staffing levels in the primary store adequate throughout the review period?		
		A. Was the storekeeper post filled throughout the period (note 1) [YES/NO].		
		B. How many technical staff should have been in-post (note 2) ?		
		C. How many technical staff were in post?		
		D. How many drivers should have been in- post?		
		E. How many drivers were in-post?		
		F. How many ancillary staff should have been in-post (note 3)?		
		G. How many ancillary staff were in-post?		
		Commentary:		
10.4.2	These staff should be adequately trained to perform the full range of tasks for which they are responsible.	**Method:** Assess staff qualifications.		
		Q6: Are the staff who are currently in post adequately trained/qualified?		
		A. Is the storekeeper adequately trained in vaccine management? [Score on a scale of 0-4].		
		B. Is the storekeeper adequately trained in stock management? [Score on a scale of 0-4].		
		C. Is the storekeeper adequately trained in logistics/operations management? [Score on a scale of 0-4].		
		D. Have technical staff received adequate training? [Score on a scale of 0-4].		
		E. Have drivers received adequate training in driving and vehicle maintenance? [Score on a scale of 0-4].		
		Commentary:		
10.4.3	Staff should be adequately motivated so as to ensure that they perform their assigned tasks diligently.	**Method**: Can only be assessed by exercising judgement.		
		Q7: Do staff appear to be well motivated? [discuss in commentary]		
		Commentary:		

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
10.5	***Wherever a contracted-out service is used, it is adequately funded and resourced and it conforms with the requirements set out in this document.***			
10.5.1	**Contracted-out services:** Where entire services are contracted out and facilities are owned and operated by others, provide evidence to show that an effective and enforceable contract is in place and that service response is acceptable.	**Method:** Review the lease/contract terms. Inspect maintenance records. Compare with evidence from physical inspection. To the extent that the clearing agent performs some or all of the tasks listed in criteria 1-9 above, score the agent's performance against the relevant questions.		

Q8: Is the contract with the service provider adequate (note 4)? [Assess each contract on a scale of 0= absent to 4= excellent. If the service is not contracted-out, enter 'n/a']

A. Vaccine storage [Score on a scale of 0-4]. ☐

B. Transport [Score on a scale of 0-4]. ☐

Commentary: ☐

Notes:

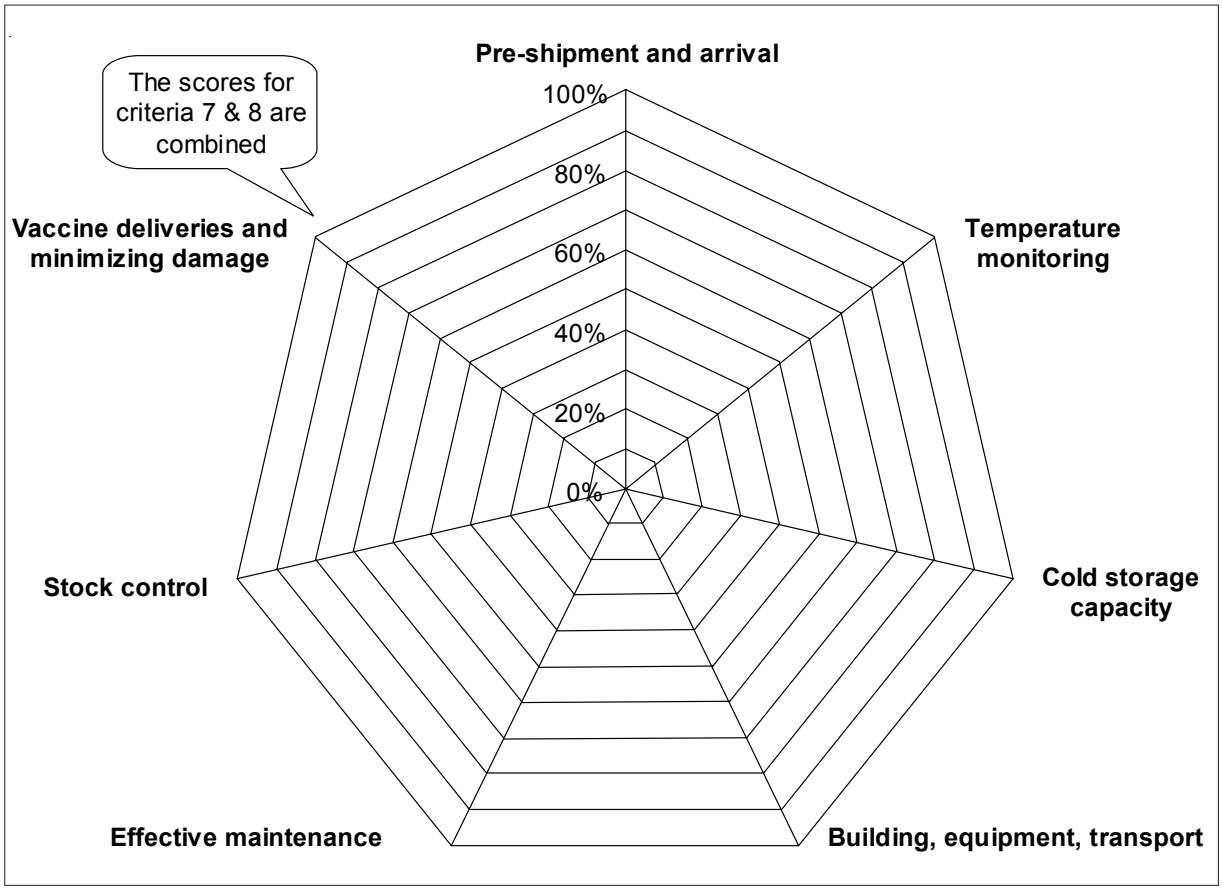
1) Q5A: Because the storekeeper has a critical management function, if this post is not filled throughout the period, the score should be 0.

2) Q5B: Technical staff include book-keepers, stock-keeping clerks, refrigeration technicians, motor mechanics, etc.

3) Q5F: Ancillary staff include cleaners, night watchmen, etc.

4) Q8: The physical performance of any contracted-out services should be assessed under criteria 1-9. All that Q8 deals with is the adequacy of the contract conditions.

Assessment results for criteria 1 to 8



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Module 4

Guidelines for self-assessment

WHO-UNICEF
Effective Vaccine Store Management Initiative

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WHO–UNICEF joint statement on effective vaccine store management (WHO/IVB/04.16)
Module 1: Ten global criteria for effective vaccine store management (WHO/IVB/04.17)
Module 2: Model quality plan (WHO/IVB/04.18)
Module 3: Assessment questionnaire (WHO/IVB/04.19)
Module 4: Guidelines for self-assessment (WHO/IVB/04.20)

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Contents

Introduction

"Guidelines for Self-assessment" is the forth of four component modules that have been developed by the Effective Vaccine Store Management (EVSM) team, with the aim of helping countries to improve their vaccine storage and distribution systems. The four modules are as follows:

1. **Ten Global Criteria for Effective Vaccine Store Management:** This document describes the background to EVSM and sets out the ten key criteria against which cold store performance is to be evaluated.
2. **The Model Quality Plan:** This document is a reference source. It takes the ten key criteria, breaks them down into sub-headings and supplements these sub-headings with supporting material.
3. **The Assessment Questionnaire:** Initially the Assessment Questionnaire will be used by national inspectors to collect data in a standardized form so that it can be analysed in a consistent manner. Once this exercise has been carried out, and the national team is satisfied that the performance of the store is satisfactory, the national manager can request an international certification inspection based on the same questionnaire.
4. **Guidelines for Self-assessment:** These guidelines are designed to help national managers to assess their own stores, using the Assessment Questionnaire. Once this exercise has been carried out, and the performance of the store is shown to be satisfactory, the national manager can request an international inspection.

1. Planning & carrying out a self-assessment

The intention of the Effective Vaccine Store Management (EVSM) is to assist programmes, in a systematic manner, to identify and correct weaknesses in store management where these exist; equally, the EVSM aims to strengthen existing practices where these are of a high standard.

Figure 1 illustrates five steps that need to be taken to adopt and to implement the EVSM initiative. Each step provides answers to the five basic questions shown on the right hand side of the diagram. The documentation and methods shown in the central section illustrate how this five step action plan can be achieved:

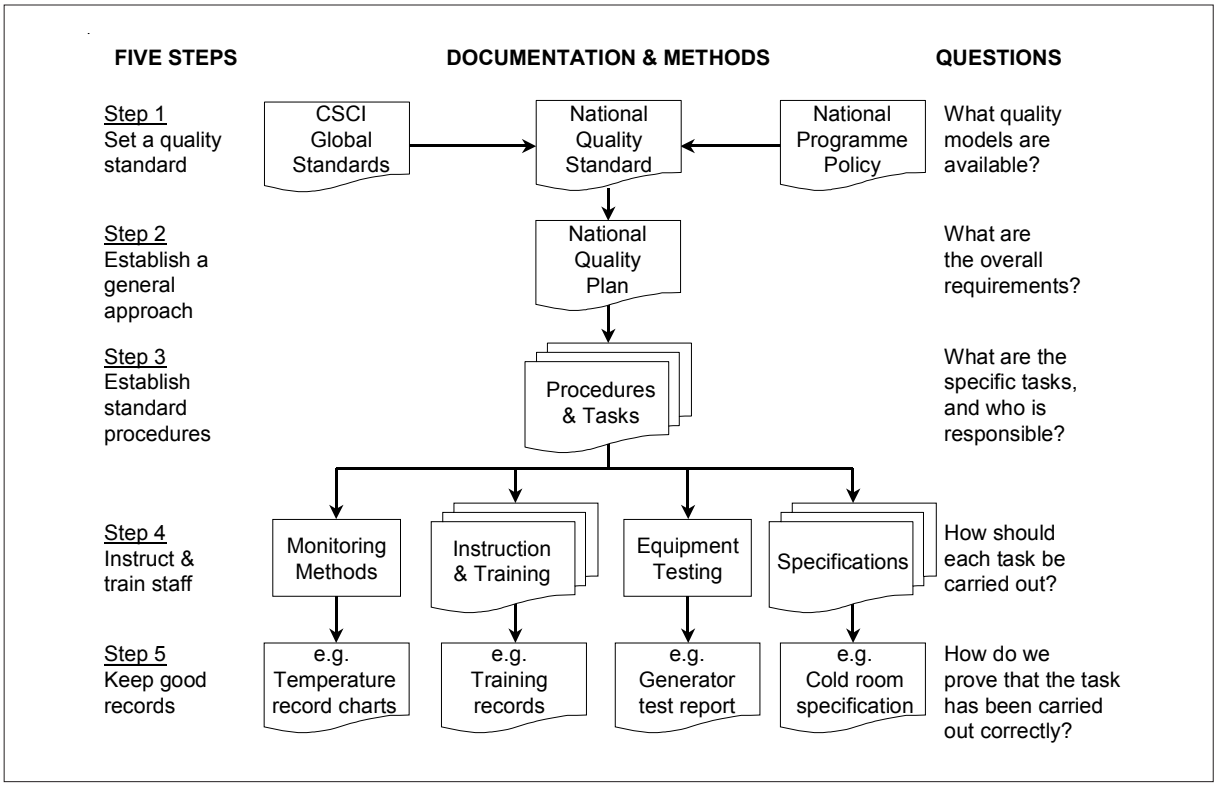
- *Step 1:* Establish a ***National Quality Standard***. This standard will be based on national programme policy guidelines and on the EVSM's ***Ten Global Criteria for Effective Vaccine Store Management***.
- *Step 2:* Prepare and adopt a ***National Quality Plan*** (NQP). The EVSM ***Model Quality Plan*** (MQP) provides a template for this. However it is expected that countries will wish to adapt the MQP to reflect local conditions, and to include existing programme standards and existing standard operating procedures where these are soundly based.
- *Step 3:* Identify the specific tasks and procedures which will achieve the standard of performance set out in the quality plan. Assign these tasks to named staff members.
- *Step 4:* Instruct and train these staff so that they can perform their assigned tasks competently.
- *Step 5:* Keep good records so that senior programme staff and international assessors can verify that the performance of the store has met the EVSM standard over an extended period.

Implementing the EVSM will require a significant management effort over a period of months. The suggested approach is as follows:

- Use the assessment tool and the MQP to carry out a rapid review of existing procedures, financial resources, staffing levels, training, buildings, equipment and transport. Identify any major weaknesses, especially in areas identified as ***critical indicators*** in the assessment tool. This preliminary assessment will become the ***benchmark*** against which future assessments can be compared.
- Make time to prepare a ***National Quality Plan*** and draw up a programme of improvements.
- Implement the improvement programme. Start with improvements to procedures, as these can often be improved quite rapidly, and at low cost. Move on to improvements in other areas as resources become available.
- When performance levels have reached an acceptable level, carry out a more formal self-assessment exercise using the assessment tool.

- Assuming that the self-assessment is satisfactory, invite an international assessment team to evaluate the store. Make sure that a full set of records exists for the twelve-month period leading up to the assessment. It is essential that these records are collected together and made available to the team so that they can carry out their work effectively.

Figure 1: How to improve the quality of vaccine store management



As has already been mentioned, implementing the EVSM will require a significant management effort. However the cost of a major loss of vaccine at a primary level vaccine store is high and is likely far to outweigh the cost of introducing the sound management methods and effective monitoring procedures advocated by the Effective Vaccine Store Management initiative.

2. The assessment tool

The EVSM Assessment Questionnaire is supplied as an Excel workbook. This is made up of fourteen worksheets as described below:

1. *Introductory notes:* A brief summary of the tool and of its revision history.
2. *Background:* Used to record basic information on the site which is being assessed. External assessors will use this worksheet to enter information collected before their inspection visit. A self-assessment team can use it in a similar manner.
3. *Human resources:* Used to collect information on the staff employed in the store, together with details of their qualifications and experience. The worksheet is also used to record the details of government-employed specialists – for example refrigeration technicians who are not part of the store's establishment, but can be called on if required. Finally it may be used to record details of any outside company or agency – for example a transport company – who is contracted to provide a service to the primary store.
4. *Ten criteria:* The worksheets, tagged C1 to C10, contain the main content of the questionnaire. Each worksheet covers one of the ten EVSM criteria described in ***Module 1 – Ten Global Criteria for Effective Vaccine Management.*** The questions themselves are grouped under a number of headings and sub-headings; each of these is set out and discussed in more detail in ***Module 2 – Model Quality Plan*** *(MQP).* The numbering system in the Assessment Questionnaire exactly follows the MQP and the two documents are intended to be used together.
5. *Spider web graph:* The last worksheet displays the numerical results of the assessment in the form of a "spider web" chart. This chart is designed to show at a glance how well the store is performing against the first eight EVSM criteria. Criteria 9 and 10 require a written assessment – they cannot be scored numerically.

The worksheets include three types of question. First there are those highlighted as ***Critical indicators***. These questions are intended to test the most fundamental aspects of vaccine store management, and for this reason each one attracts a high score. A low score against a critical indicator provides strong evidence that an aspect of store management is dangerously weak and that significant improvements need to be made.

The second group of questions evaluates aspects of store management which, although less critical than the first group, nevertheless provide evidence of good management practice. These questions are also scored numerically.

The third group of questions requires a written commentary. Most of these questions deal with broader issues, such as financial management and resources. As noted above, the majority of the questions of this type are listed under Criteria 9 and 10.

Note that numerical scoring is only part of the evaluation exercise. It is essential that assessors also record their observations in written form. For this reason every question, or group of questions, is followed by a *Commentary* box in which assessors can amplify and qualify their findings. These commentaries are intended to form part of the content of the assessment report which will accompany every EVSM evaluation.

Satisfactory performance level for each criterion is set as 80%.

Figure 2 shows an annotated extract from the questionnaire.

Figure 2: Annotated extract from assessment questionnaire

2 Over a period of 12 months, all vaccines have been stored within WHO recommended temperature ranges.

Note to assessors: There are a number of unforseeable ways in which vaccine may be damaged or lost during storage which do not necessarily reflect badly on the system - for example, accidental damage during handling. To take account of such events, question **Q5** allows a percentage loss without prejudicing the overall score. However, where such losses have occurred, it is essential that the assessors inquire as to the cause(s) and record this in the commentary. If the main reason for the loss is a system failure then this should be stated and may be used as justification to downgrade the score.

Ref	REQUIREMENTS	ASSESSMENT METHOD		RESULTS	SCORE
2.1	***Continuous temperature records are available, and these records demonstrate that vaccine has been stored correctly in both permanent and temporary cold stores.***				
2.1.1	Store all vaccines and diluents at the correct temperature	**Method:** Interview staff, inspect training records			
		Q1:	***Critical indicator:*** Does the storekeeper know the correct storage temperature range for each of the vaccines on the schedule (see note 1)? [YES=1, NO=0]	1	5.00
		Q2:	***Critical indicator:*** Does the storekeeper know the freezing temperature of all the freeze-sensitive vaccines on the schedule (see note 2)? [YES=1, NO=0]	1	5.00
		Q3:	Has the storekeeper received formal or on-the-job training in how to look after vaccines? [YES=1, NO=0]	0	0.00
		Q4:	Have all other staff who are responsible for looking after vaccines received such training? [YES=1, NO=0. If no other responsible staff, enter "n/a"]	0	0.00
		Commentary:	Q3 & Q4 : Interviews with staff suggest that training in vaccine management is weak.		
2.1.2	Use stock records to demonstrate that all vaccines and diluents have been stored in accordance with current WHO storage temperature recommendations.	**Method:** Inspect stock records			
		Q5:	***Critical indicator.*** Collect the following information to establish the percentage of doses that have been discarded as a consequence of incorrect storage conditions during the review period (note 3).		
		A.	Record number of doses of all vaccines in stock at the start of the review period.	1,000,000	
		B.	Record number of doses of all vaccines received during the review period.	1,000,000	
		C.	Record number of doses issued during the review period.	0	
		D.	Record number of doses of all vaccines discarded because of incorrect storage temperatures.	5,000	
		E.	Record number of doses of all vaccines in stock at the end of the review period.	2,000,000	
		END BALANCE CHECK:	Based on these figures, the end balance should be 1,995,000 doses. If it is not, query the stock records.		
		F.	If the percentage discarded is greater than 1% score is set = 0. If equal to or less than 1%, score = 5.	0.25%	5.00
		Commentary:	Discrepancy of 5000 doses could not be reconciled. Refer to Qs on stock management for further comments on this topic, showing weaknesses in this area of store management		

Suggested evaluation method

Critical indicators highlighted in colour

Enter results in these cells

Detailed requirement and related assessment questions. Refer to MQP for more information

Protected fields shaded grey

Automatic check