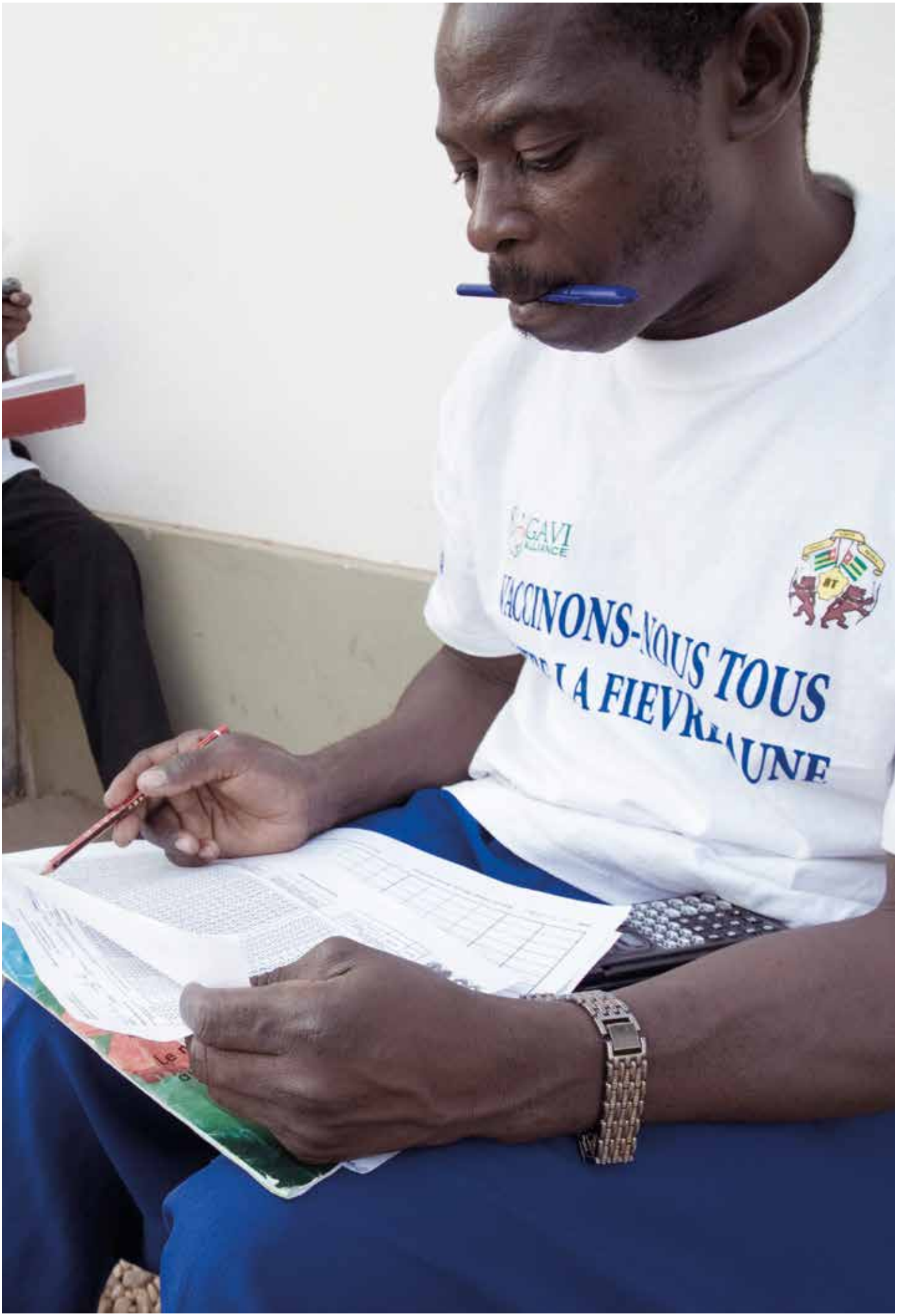
Mid-Level Management Course for EPI Managers

BLOCK III: Logistics

Module 7: Cold chain management

World Health Organization
REGIONAL OFFICE FOR Africa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Mid-Level Management Course for EPI Managers

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Module 7: Cold chain management

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Abbreviations and acronyms

AFP	acute flaccid paralysis
BCG	Bacillus Calmette-Guérin (vaccine against TB)
CFC	chlorofluorocarbon
DANIDA	Danish International Development Agency
DT	diphtheria-tetanus vaccine
DTP	diphtheria-tetanus-pertussis-containing vaccine
EEFO	earliest expiry first out
EPI	Expanded Programme on Immunization
EVM	effective vaccine management
FCV	full course vaccination
FIC	fully immunized child
Gavi	Global Alliance for Vaccine and Immunization
HepB	hepatitis B vaccine
Hib	*Haemophilus influenzae* type b vaccine
ILR	iceline refrigerator
IMCI	Integrated Management of Childhood Illness
IPV	inactivated polio vaccine
MDVP	multi-dose vial policy
MMR	measles, mumps, rubella vaccine
MOH	ministry of health
MR	measles, rubella vaccine
NESI	Network on Education and Support in Immunisation
NIP	national immunization programme
NVI	new vaccine introduction
OPV	oral polio vaccine
PPP	public-private partnership
PQS	product quality and safety
RED/REC	Reaching Every District/Reaching Every Community
SDG	Sustainable Development Goal
SOP	standard operating procedure
TT	tetanus toxoid
UNICEF	United Nations Children's Fund
VVM	vaccine vial monitor
WHO	World Health Organization

Glossary

Bundling — A concept which requires that certain items must be ordered, distributed and used together. In the case of immunization, this concept applies to vaccines, diluents, syringes, needles and safety boxes. It does not necessarily apply that things are tied together physically.

Cold chain — Cold chain is a system of different elements, i.e. human, material and financial resources, and certain norms and standards that ensure the high quality of vaccines. Cold chain consists of different levels called links, which deal with vaccine orders and supplies, their transportation, storage and distribution from factory to the point of administration to the target population.

Inventory — A physical count and assessment of the state and the functionality of the equipment and other materials used in cold chain.

Logistics — A group of operations that includes procurement, delivery of vaccines and consumables to the place of their use, management and maintenance of transport and cold chain equipment.

Maintenance — A series of technical activities (preventive and "curative") that ensures smooth running of the equipment and transport facilities (related to cold chain).

Reverse cold chain — This is a special chain, which starts from taking specimens, preserving and transporting them, from the patient to the laboratory.

Supervision — Supervision is a process to guide, support and assist service providers to carry out their duties and assigned tasks so as to achieve planned organizational goals. The process is based on observations, interviews, inspections, review of documentation that helps supervisors to assess the situation, and health workers to improve performance.

Vaccine — Biological product prepared from killed or attenuated (weakened) virus or bacteria or their toxins, used for vaccinating people to induce specific immunity against an infectious disease.

1. Introduction

1.1 Context

The Expanded Programme on Immunization (EPI) is a key global health programme. Its overall goal is to provide effective and quality immunization services to target populations. EPI programme managers and staff need to have sound technical and managerial capacities in order to achieve the programme's goals.

The immunization system comprises five key operations: service delivery, communication, logistics, vaccine supply and quality, and surveillance. It also consists of three support components: management, financing and capacity strengthening.

National immunization systems are constantly undergoing change, notably those related to the introduction of new vaccines and new technologies, and programme expansion to reach broader target populations beyond young children. The EPI programme also faces external changes related to administrative decentralization, health reforms, as well as the evolving context of public-private partnerships (PPPs) for health, among others.

To ensure the smooth implementation of immunization programmes, EPI programme staff have to manage these changes. This requires specific skills in problem-solving, setting priorities, decision-making, planning and managing human, financial and material resources as well as monitoring implementation, supervision and evaluation of services.

National immunization programmes (NIPs) operate within the context of national health systems, in alignment with global and regional strategies. For the current decade, 2011–2020, the key global immunization strategies are conveyed through the Global Vaccine Action Plan (2011–2020) (GVAP) and the African Regional Strategic Plan for Immunization (2014–2020) (RSPI).

These strategic plans call on countries to:

- improve immunization coverage beyond current levels;
- complete interruption of poliovirus transmission and ensure virus containment;[1]
- attain the elimination of measles and make progress in the elimination of rubella and congenital rubella syndrome;[2] and
- attain and maintain elimination/control of other vaccine-preventable diseases (VPDs).

The key approaches for implementation of the GVAP/RSPI include:

- implementation of the Reaching Every District/Reaching Every Community (RED/REC) approach and other locally tailored approaches and move from supply-driven to demand-driven immunization services;
- extending the benefits of new vaccines to all;
- establishing sustainable immunization financing mechanisms;
- integrating immunization into national health policies and plans;
- ensuring that interventions are quantified, costed and incorporated into the various components of national health systems;
- enhancing partnerships for immunization;
- improving monitoring and data quality;
- improving human and institutional capacities;
- improving vaccine safety and regulation; and
- promoting implementation research and innovation.

The RSPI promotes integration using immunization as a platform for a range of priority interventions or as a component of a package of key interventions. Immunization is a central part of initiatives for the elimination and eradication of VPDs, and of the integrated Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea (GAPPD) by 2025.

It is understood that while implementing the above strategies, EPI managers will face numerous challenges and constraints that they need to resolve if the 2020 targets are to be met. Building national capacity in immunization service management at all levels of the health system is an essential foundation and key operational approach to achieving the goals of the global and regional strategic plans.

In view of this, the WHO Regional Office for Africa, in collaboration with key immunization partners such as the United Nations Children's Fund (UNICEF), United States Agency for International Development (Maternal and Child Survival Program) (USAID/MCSP), and the Network for Education and Support in Immunisation (NESI), have revised the Mid-Level Management Course for EPI Managers (MLM) training modules. These modules are complementary to other training materials including the Immunization in Practice (IIP) training manuals for health workers and the EPI/Integrated Management of Childhood Illnesses (IMCI) interactive training tool.

1 WHO, CDC and UNICEF (2012). Polio Eradication and Endgame Strategic Plan 2013-2018.
2 WHO (2012). Global Measles and Rubella Strategic Plan 2012-2020.

This module (7) titled *Cold chain management* is part of Block III: Logistics.

1.2 Purpose of the module

This module provides field staff with up-to-date information about the cold chain. It is a practical teaching tool for health staff working in immunization, whatever their level, to manage logistics support for EPI and to provide quality services to the target populations.

1.3 Target audience

This module is for EPI staff at all levels of the national health system as well as for teachers in training institutions. It provides EPI staff with the information needed to manage cold chain equipment and to train personnel in supportive supervision and monitoring of the cold chain.

1.4 Learning objectives

At the end of the module, the participants should be able to:

- Explain the cold chain:
  - justify the choice of the selected of cold chain options and equipment
  - estimate cold chain capacities and select the equipment.
- Calculate the storage requirements of vaccines at various levels:
  - assess the freezing capacity of the equipment for coolant packs
  - select appropriate cold chain equipment.
- Manage the cold chain:
  - set the vaccine supply schedule, taking into account the storage capacity of the equipment
  - establish record keeping and implement physical count
  - determine conditions for equipment maintenance at various levels.
- Evaluate cold chain operational needs:
  - assess replacement needs of cold chain equipment.
- Prepare plans for cold chain:
  - elaborate an annual cold chain plan
  - prepare an emergency plan for cold chain.
- Monitor cold chain operations:
  - formulate key performance indicators for cold chain operations
  - establish a dashboard for monitoring of the cold chain.
- Supervise the cold chain:
  - set up a checklist for cold chain supervision.
- Determine the technical tasks to be carried out by health workers for cold chain maintenance:
  - prepare a training programme or refresher course for health personnel.

1.5 Contents of the module

This module contains the sections shown below.

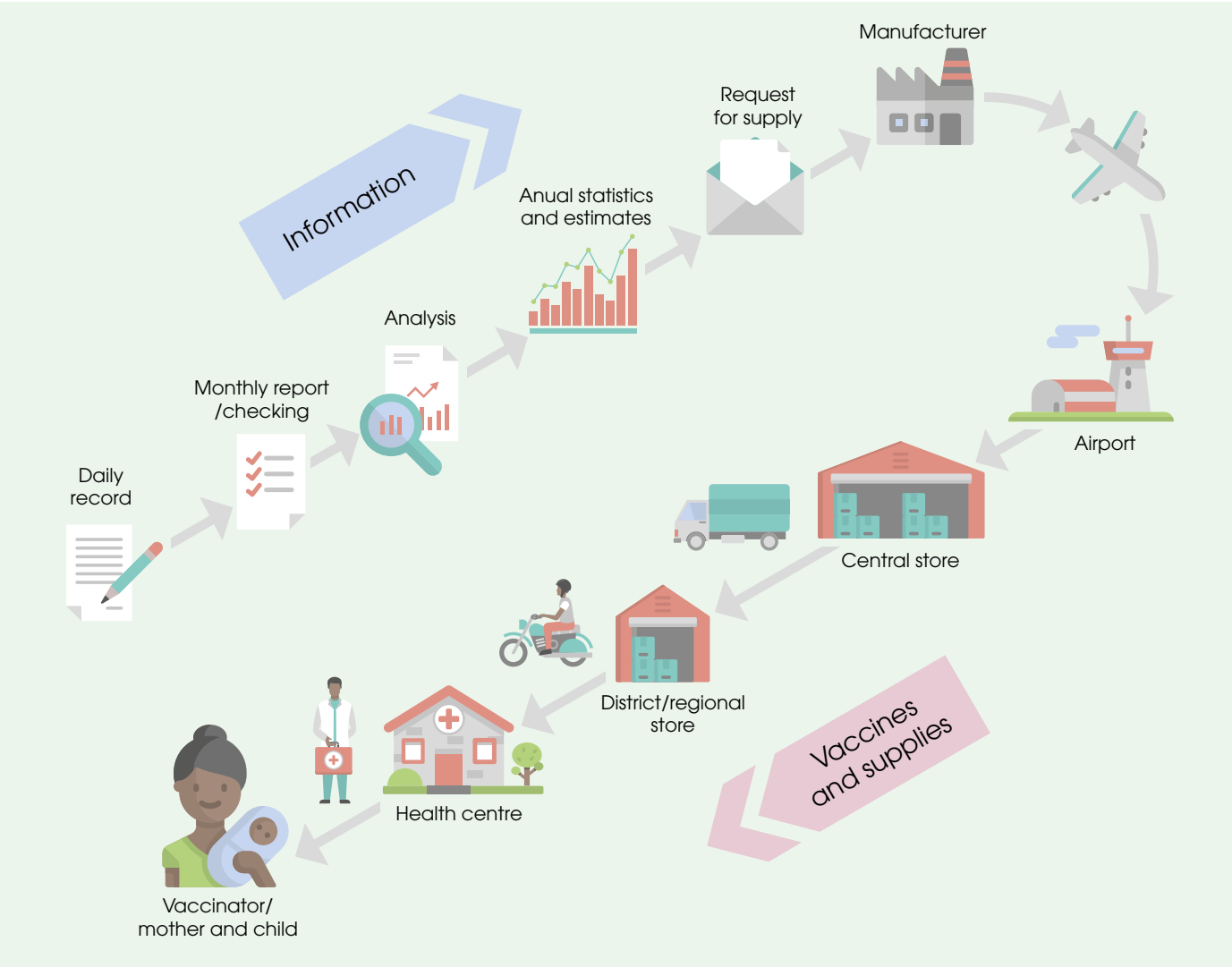
1.6 How to use this module

After discussion of the main management concepts of the cold chain and consideration of the various approaches suggested, each participant will proceed to the practical exercises. With the help of the facilitator, the working group or plenary session will discuss and comment on the exercises.

2. Organizing the cold chain

The cold chain is a system of different elements, i.e. human, material and financial resources, and certain norms and standards that ensure the high quality of vaccines. Cold chain consists of different levels called links, which deal with vaccine orders and supplies, their transportation, storage and distribution from factory to the point of administration to the target population. Figure 2.1 illustrates this chain in detail.

Figure 2.1 Vaccine movement in the cold chain from manufacturers to the target child or woman



The cold chain is an integral part of any immunization programme and, as such, it should be considered within the entire EPI management framework (planning, monitoring and evaluation).

During the planning of immunization activities, EPI management should:

- determine the best possible cold chain option; and
- ensure the availability of high-quality vaccines (including new vaccines) at all levels in the country.

2.1 Cold chain options

Effective vaccine management (EVM) assessment and cold chain mapping can be used to determine the most appropriate cold chain system. Two options are proposed in this module: **slow cold chain** and **fast cold chain** (see Table 2.1).

Table 2.1 Cold chain options

	Slow cold chain	Fast cold chain
Definition	The slow cold chain relies on cold-generating equipment (e.g. cold rooms, refrigerators, freezers, etc.). The slow cold chain will reduce the costs of vaccine distribution, but increase the quantity in circulation. However, with the low cold chain, the vaccine distribution system/transport is expensive and, if not properly maintained, unreliable.	The fast cold chain option is based on the use of passive containers (not cold-generating but ones that maintain it), e.g. cold box, vaccine carrier, etc. used for temporary storage of vaccines. The fast cold chain relies on speed to minimize the gaps in vaccine storage, distribution and handling. The fast cold chain can lead to higher transportation costs, but these are compensated partly by cheaper storage costs.
Conditions	• Refrigeration at the health centre level is reliable • Stock management system is adequate • Good warehousing practices are in place • This system uses ice-making equipment (such as refrigerators, freezers or cold rooms)	• Refrigeration at health facility level is not reliable • Stock management system is inadequate • Poor warehousing practices • Vaccine distribution system/transport in place is reliable and quite cheap • Vaccines to distribute and use are costly (e.g. Hib, HepB, PCV, rota, etc.)

It is not necessary and practical to choose one option for the entire country. Based on the specific situation in each district, some will choose the fast cold chain and others the slow cold chain. A combined plan can also be made: slow cold chain between the central and province/district stores, fast cold chain between the district stores and the health centres. Outreach and campaigns are implemented using mainly the fast cold chain option.

Exercise 1

For all groups.
You are in charge of a district with 30 health centres, including:

- **Health centre A:** Situated 60 km from the district health centre, with a population of 15 000; during the rainy season the centre is inaccessible and does not have a refrigerator. Your request for refrigerators has not been granted by higher officials.
- **Health centre B:** Within 5 km and is along the main road, with a population of 20 000. It has its own refrigerator but no cold chain technician to make repairs. The officer in charge of the health centre informed you by telephone that the vaccine refrigerator is broken.
- **Health centre C:** 15 km from the district health centre, with a population of 5000. It has a refrigerator. However, during a recent supervision visit, you established that there is only one health officer at the centre and they do not have any tools for cold chain repair or monitoring.

Task 1: What measures are you going to put in place to ensure that immunization is not interrupted in any of the centres?

Task 2: Which cold chain option, in your opinion, would be most suitable for these situations?

Support your decision at the plenary.

2.2 Supply of vaccines and other EPI materials

The organization of supply is an integral part of the overall cold chain system, and should be properly planned and executed. There are two types of supply procedures: collection and dispatch (see Table 2.2):

Collection: Vaccines and other supplies are collected by the user health facility (pull system).
Dispatch: Supplies are delivered to the user health facility (push system).

Table 2.2 Types of supply procedures

	Collection (pull system)	Dispatch (push system)
Advantages	• User can collect whenever vaccine is needed • Collectors are involved in safe packaging and transportation • Collectors can, at the point of collection, verify whether quantities supplied correspond with quantities requested • Collection can be combined with other activities (i.e. review meetings, payment of salaries, etc	• Push system brings down transport costs due to optimized delivery routes • Integration with other supplies • Supportive supervision can be combined with the delivery • Check on sight the stock levels • Data on vaccine movement can easily be collected
Constraints (disadvantages)	• Collection requires additional transport, fuel, time and funds for vaccine supply for each facility • Pull system may cause lack of coordination by vaccine store at higher level • Opportunities for supervisory visits are reduced	• Delivery system requires larger transport capacity • In certain circumstances, a refrigerated vehicle may be needed to ensure safe deliveries • Risk of loss of large quantities of vaccine due to breakdown or accident is higher

In practice, a combination of the two supply methods may achieve more flexibility in the supply system. Uniformity of the mode of supply is unlikely because it depends on local conditions. Whatever the chosen mode of supply, it should ensure an uninterrupted supply for every service delivery point.

2.2.1 Packaging vaccines for transportation

Staff in charge of vaccine handling (storage and transportation) must be properly trained in vaccine packaging. The following options are recommended[3] regarding the use of coolant packs for the transportation of vaccines to ensure their quality:

- **Frozen ice packs:** This option can be used to transport all lyophilized vaccines, or any liquid vaccine that is NOT freeze sensitive, such as oral polio vaccines (OPVs). Frozen ice packs must NEVER be used to transport a freeze-sensitive vaccine or a lyophilized vaccine that is packaged with its diluent.

- **Conditioned ice packs:** This option can be used to transport any vaccine, including lyophilized vaccines with bundled diluents. However, the ice packs MUST be conditioned correctly, as described in Module 8: *Vaccine management.*

- **Cool water packs:** If the vaccine has a vaccine vial monitor (VVM), this option can be used for transport between the primary store and the health facility for any vaccine EXCEPT those with a VVM 2 or VVM 7; this includes OPVs, some brands of inactivated poliovirus vaccine (IPV) and varicella vaccine. For outreach purposes, cool water packs can be used for ALL vaccines that carry a VVM.

- **Cool water packs for sub-zero protection in unheated vehicles:** For short journeys in sub-zero temperatures, cool water packs will protect both liquid freeze-sensitive vaccines and vaccine diluents against the risk of freezing. They can safely be used for this purpose even when the vaccine does not have a VVM.

- **Warm water packs for sub-zero protection in unheated vehicles:** For long journeys in sub-zero temperatures, warm water packs are needed to prevent most liquid freeze-sensitive vaccines and vaccine diluents from freezing, provided the vaccines have VVMs. However, warm water packs should NEVER be used to transport OPV, IPV with VVM 7, varicella or any other highly heat-sensitive vaccine. They should also NEVER be used for any vaccine without a VVM because there is no way to monitor the effect of exposure to temperatures above the labelled storage range of +2°C to +8°C.

Tables 2.3 and 2.4 summarize the use of coolant packs options for vaccines with and without VVMs.

3 WHO/HQ (2015). Vaccine Management Handbook Module VMH-E7-02.1 How to use passive containers and coolant packs for vaccine transport and outreach operation.

Table 2.3 Coolant packs options for vaccines with VVMs

Product	Frozen ice packs	Conditioned ice packs	Cool water packs	Warm water packs
Transport from primary store to health facility				
Liquid vaccines: freeze sensitive		✓	✓ (at sub-zero ambient)	✓ (at sub-zero ambient)
Liquid vaccines: NOT freeze sensitive	✓	✓	✓ (for greater than VVM 7)	
Lyophilized vaccines: separate diluent	✓	✓	✓ (for greater than VVM 7)	
Lyophilized vaccines: packed with diluent		✓	✓ (for greater than VVM 7)	✓ (at sub-zero ambient)
Diluent packaged alone		✓	✓	✓ (at sub-zero ambient)
Transport to outreach sessions				
Liquid vaccines: freeze sensitive		✓	✓	
Liquid vaccines: NOT freeze sensitive	✓ (for campaigns)	✓	✓	
Lyophilized vaccines with diluent		✓	✓	

Table 2.4 Coolant packs options for vaccines without VVMs

Product	Frozen ice packs	Conditioned ice packs	Cool water packs	Warm water packs
Transport from primary store to health facility				
Liquid vaccines: freeze sensitive		✓	✓ (at sub-zero ambient only)	
Liquid vaccines: NOT freeze sensitive	✓	✓		
Lyophilized vaccines: separate diluent	✓	✓		
Lyophilized vaccines: packed with diluent		✓	✓ (at sub-zero ambient only)	
Diluent packaged alone		✓	✓	✓ (at sub-zero ambient)
Transport to outreach sessions				
Liquid vaccines: freeze sensitive		✓	✓ (except for RotaTeq®)	
Liquid vaccines: NOT freeze sensitive	✓	✓	✓	
Lyophilized vaccines with diluent		✓	✓	

2.2.2 Types of transport systems

There are three types of transport system to choose from:

- a ministry of health (MOH) managed and operated (centralized) transport network;
- a blend of public and government sector transport network; or
- an outsourced private sector transport service provider. Several outsourced scenarios can be considered:
  - fully outsourced service provider where vehicles are owned, managed and operated by service provider (rental car model);
  - MOH owns vehicles which are operated and maintained by private service provider; or
  - MOH manages vehicle operations, with private service provider carrying out just service and maintenance of the vehicle.

Table 2.5 Choosing appropriate transport

	MOH managed and operated	Public-private	Outsourced service provider
Advantages	• Directly controlled by MOH • In-house maintenance service can include service of cold generating units, be linked to vaccine supply etc. • Vehicles can be shared with/for other programmes	• Reduced call on MOH capital assets • Cost-effective scenario when domestic air or boat transport is required • Reduced MOH responsibilities for maintenance/service of specialized equipment (i.e. refrigerated trucks) • Generally more cost efficient than a MOH managed and operated system	• Transfers vehicle operations and management responsibility to experienced provider operating in the sector • Vehicle life extended by 40–60% due to high maintenance standards • Removed liability of asset and diversification of core competence from MOH • Generally lower cost option for MOH and higher quality transport network
Disadvantages	• Diverts MOH expertise away from core competence • Cost increase due to substantial operational responsibilities for fuel supply and maintenance services • Tendency for vehicle use to be diverted from providing EPI services	• Requires MOH close monitoring and control of private sector operations • Transport to be provided by private sector may not be available when required • Risks that goods assigned to private carriers are damaged or lost • Private carrier operators are not trained in vaccine transport practices	• Requires important changes to traditional practices • Requires experienced reliable service provider • Requires financial guarantees to ensure that both parties meet obligations • Outsourced operators are not trained in vaccine transport practices

2.3 Energy sources for the cold chain

The following factors should be considered when choosing an energy source for the cold chain:

- Availability, reliability and cost of different sources of energy: electricity from grid or generators, gas, kerosene/paraffin, solar energy or combinations of the above.
- Capital and running costs of different technologies: compression (electric, solar) or absorption (electric, gas, kerosene). Absorption units are often mixed, they can combine two sources of energy, (kerosene, gas and electricity) but do not operate on both at the same time.
- Availability of qualified technicians to install and maintain different refrigeration equipment.
- Safety.

Figure 2.2 summarizes the process of choosing suitable energy sources based on the availability and efficiency of refrigeration systems.

Figure 2.2 Choosing a suitable source of energy

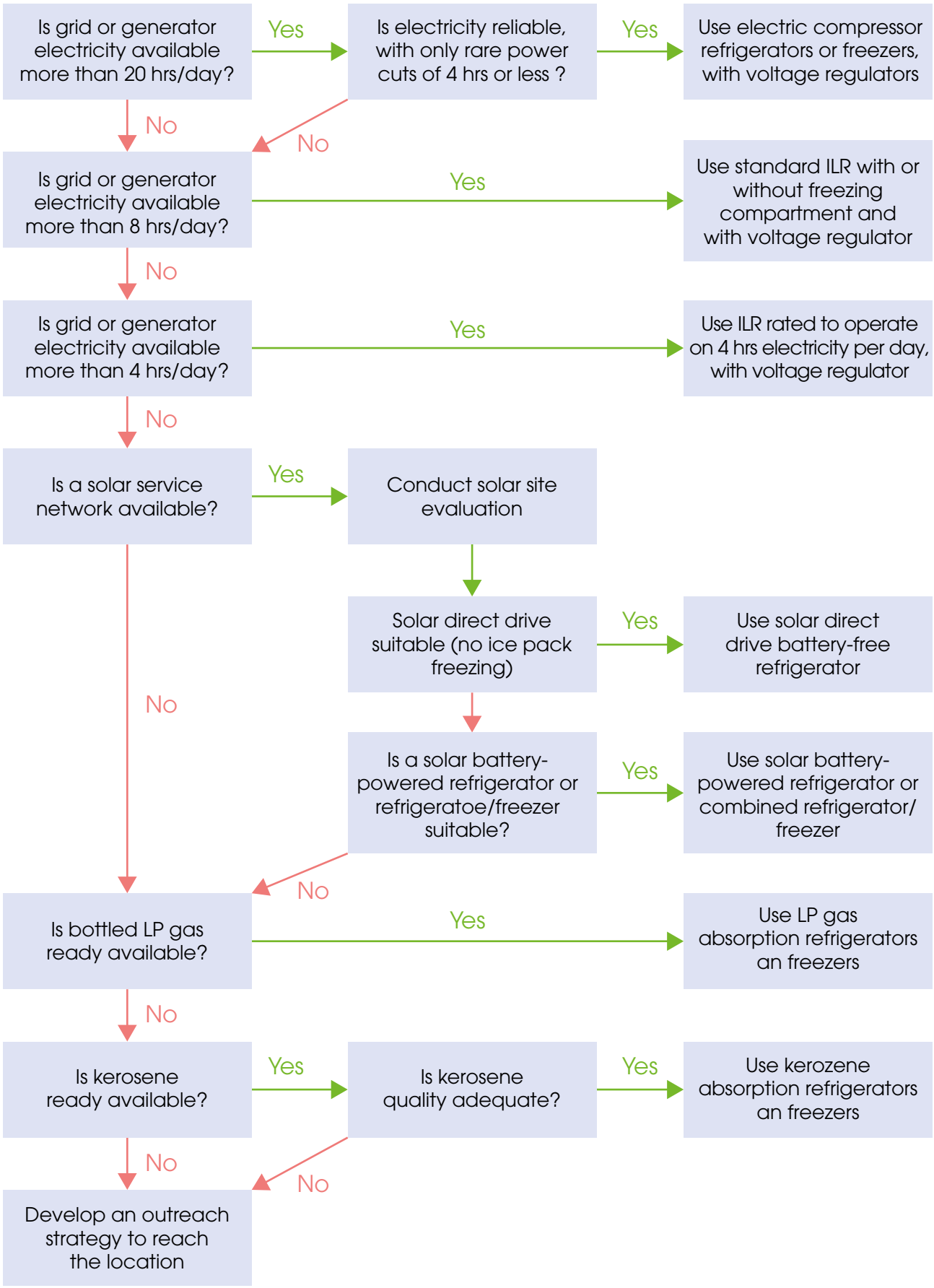


Table 2.6 Summary of advantages and disadvantages of different types of refrigerators

	Advantages	Disadvantages
Compression	• Very little routine maintenance required • The overall cost is lower than absorption type for compression types running on electricity or solar direct drive • Better performance (cold capacity and thermostatic control) than absorption type • Expertise widely available for repair	• Voltage regulator required if not in-built refrigerator • High cost for solar battery powered compression cycle • To power solar battery, it requires an established solar service network and good solar site evaluation
Absorption	• Works with more than one source of energy (kerosene or gas and electricity) • Useful for places without regular electricity supply, or when solar is not an option	• No models in WHO/PQS pre-qualified list • Overall cost is higher than compression type • Requires regular maintenance especially for kerosene models • Low cold capacity and thermostatic control is limited (gas models) or inexistent (kerosene models) • If gas leakage, it can't be repaired
Front-opening	• Vaccine arrangement easier	• High/fast cold loss when opening for models with no drawer • Door gasket maintenance is critical
Top-opening	• Very low cold loss when opening door or if gasket moderately damaged	• Vaccine arrangement not easy especially by batch/expiry date • High risk of freezing especially at the bottom if vaccine baskets are removed
Ice-lined	• Longer hold over time • Less electricity availability required (less than eight hours for most models)	• Heavy and big external volume due to the water packs/tubes in the side walls • Need for water level control of the packs/tubes

2.4 Reverse cold chain

For disease surveillance depending on the disease, specimens of stools, blood, cerebrospinal fluid or nasopharyngeal secretions may be required from suspected patients. In general, specimens should be shipped to the reference laboratory as soon as possible and shipment should not be delayed for the collection of additional specimens. For safety reasons, proper guidelines should be applied for the collection and shipment of specimens.

This special chain, which starts from taking specimens, preserving and transporting them from the patient to the laboratory, is called **reverse cold chain**. The fast cold chain is the recommended option to apply for the reverse cold chain. Two examples follow – the transport of a serum sample and a stool sample.

Serum collection for the confirmation of measles and rubella laboratory diagnosis: Blood sampling for serum collection should be done by venipuncture in a sterile tube (5 ml for older children and adults; 1 ml for infants and younger children). The sample should be centrifuged (1000 x during for 10 minutes) to obtain serum. The serum sample can be kept until shipment for a maximum of seven days in the refrigerator between 4°C and 8°C. If kept longer than seven days, the serum sample must be frozen (-20°C). If there is no centrifuge available, the whole blood sample should be stored in the refrigerator no longer than 24 hours between 4°C and 8°C in order to clot, to obtain serum. The serum samples should be transported in an insulated container with frozen packs.

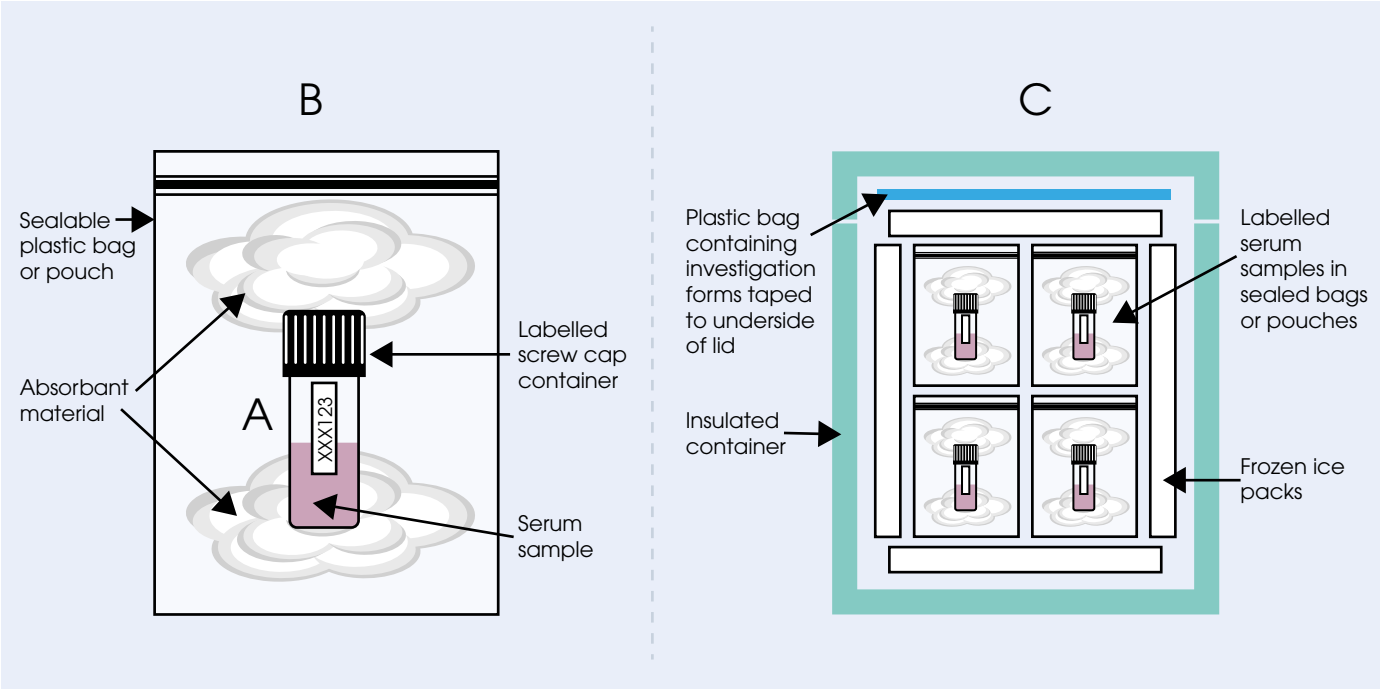
The triple packaging system should be applied for serum samples potentially containing measles and rubella virus (Figure 2.3). The labelled tubes containing the serum (package A), should be put in a sealable plastic bag or pouch (package B) with absorbent materials such as cotton wool (to soak up leakage that may occur). Insulated containers, in this case the cold box (package C), should be used to contain the sealed bags or pouches of specimens for shipment. The specimen form and investigation form for each specimen should be placed in a separate plastic bag and taped securely to the inner surface of the top of the insulated container. The frozen packs should be placed at the bottom and along the sides of the insulated container. The samples should then be placed in the centre and more ice packs placed on top. The reference laboratory should be informed of the arrival date of the samples.

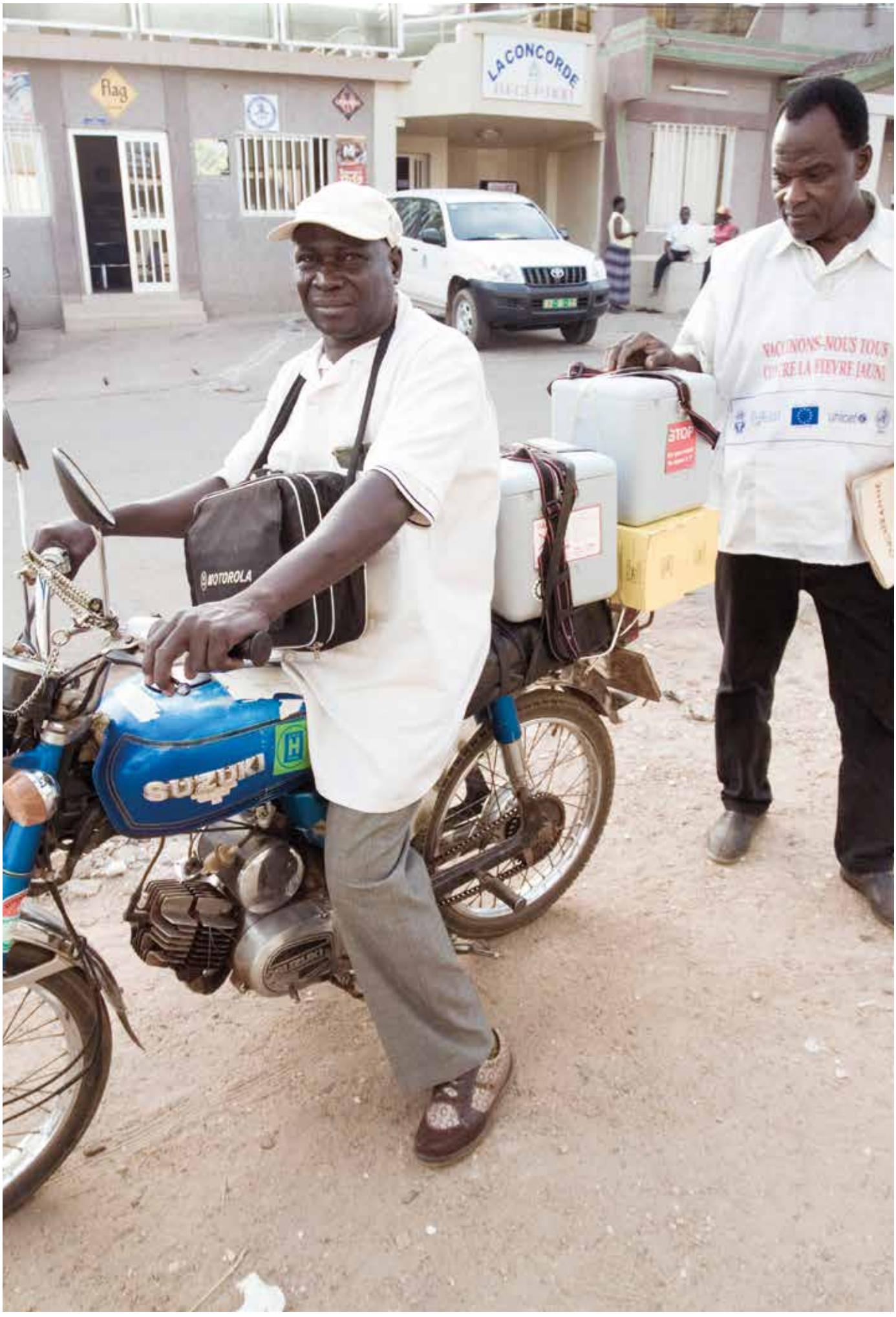
Transport of stool samples from patients with acute flaccid paralysis (AFP): The specimens should arrive at the laboratory within 72 hours of collection. If this is not possible, the specimens must be frozen (at -20°C). Shipment of the samples should be done with frozen packs in a special specimen collection carrier. If the health facility does not have a specimen collection carrier, a vaccine carrier can be used to transport specimens. The vaccine carrier containing the specimen, must be marked clearly and never be used again to transport vaccines. If a reverse cold chain is not properly maintained at all times during transport, polioviruses will not survive in the stool specimen. As with the serum for measles and rubella detection, the triple package system should be applied.

The label of the specimen collection carrier should clearly indicate the name, address and telephone number of the receiving laboratory or person. If the specimen must pass through a district hospital, the vaccine carrier must be clearly labelled and the cold chain maintained throughout. District hospitals should follow the same storage guidelines and rules as highlighted for health centres. After you have collected the specimen for investigation, inform the receiving laboratory in advance. If sending by air, investigate procedures with flight authorities in advance to avoid unnecessary delays. Specimens must never be put in cold boxes together with vaccines or other medicines.

The specimens are potentially infectious and should be handled with care. They must be labelled CONTAMINATED.

Figure 2.3 Packaging conditions for transport of serum samples

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MOTOROLA
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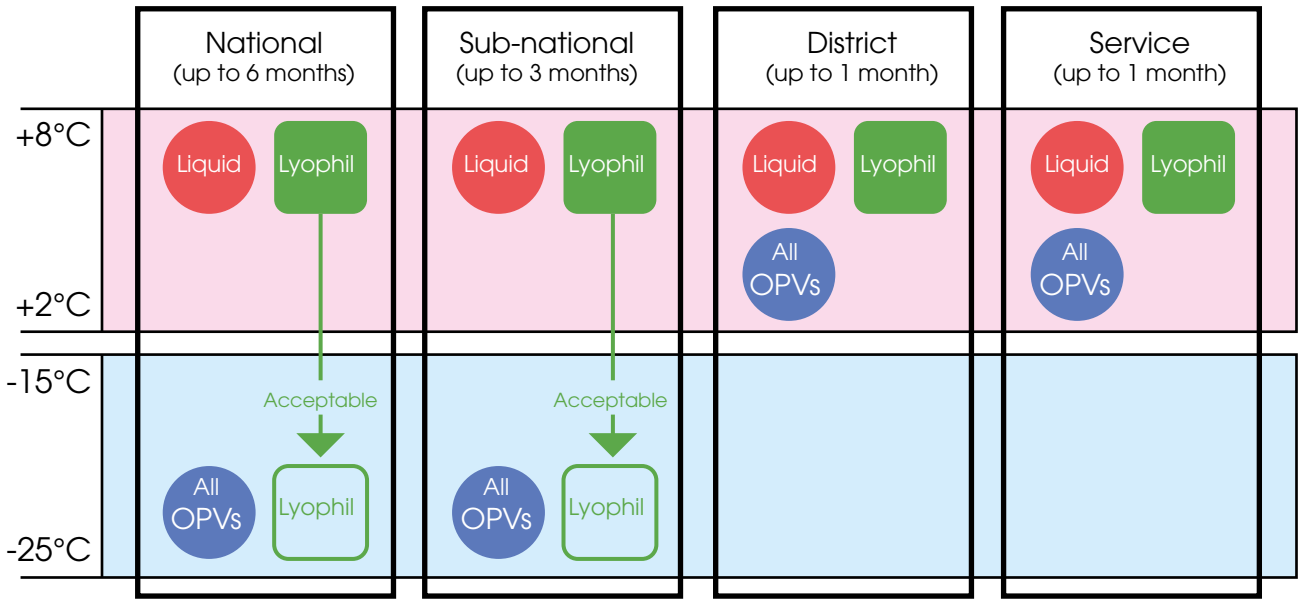
3. Estimating cold chain storage capacity

3.1 Assessing required temperature storage conditions

Each vaccine has its own storage conditions. It is important to know how long and in what quantities each vaccine can be stored at each level:

- positive temperatures, between +2°C and +8°C; or
- negative temperatures of -15°C to - 25°C.

Figure 3.1 WHO recommended storage temperatures and storage durations for vaccines and diluents



Lyophil

Lyophilized vaccines

BCG
Hib (freeze-dried)
Japanese Encephalitis (live attenuated)
Measles
Measles - Mumps - Rubella (MMR)
Measles - Rubella (MR)
Meningococcal A
Rabies (freeze-dried)
Rotavirus (freeze-dried)
Varicella
Yellow fever

Liquid

Liquid vaccines

Cholera
DT
DTP
DTP - HepB
DTP - HepB - Hib
Hep A
Hep B
Hib (liquid)
HPV
IPV
Influenza
Meningococcal ACYW
Pneumo conjugate vaccine (PVC)
Rabies (liquid)
Rotavirus (liquid)
Tetanus toxoid
Td
Typhoid PS

Note : Diluents should never be frozen. If diluents are packaged with vaccine, the product should be stored at +2°C to +8°C.
Bundled lyophilized - liquid combination vaccines should never be frozen and should be stored at +2°C to +8°C.

The following points should be noted:

- The suggested length of storage in Figure 3.1 reflects maximum recommended values. The manufacturers' expiry dates must be respected.
- Apart from the dangers of heat exposure, freezing can cause serious damage to the following vaccines: DTP, DT, TT, DTP-combo, PCV, inactivated polio, hepatitis B (hepatitis B vaccine freezes at about -0.5°C) and rota conjugate vaccines.
- Once the vaccine potency is lost through exposure to heat or freezing, it is irreversible. If the vaccine has been damaged by heat exposure, the appearance of the liquid may not necessarily change but the change in VVM colour will show the damage. If the quantity of suspect vaccine is huge, a laboratory test should be conducted to determine the loss of potency. If the vaccine is suspected to have been damaged by freezing, a shake test should be conducted.

In order to maintain vaccine quality, it is essential to monitor the temperature of vaccines throughout the supply chain. Effective monitoring and record keeping achieves the following objectives:

- Verification that vaccine storage temperatures are within the acceptable ranges of +2°C to +8°C in cold rooms and vaccine refrigerators and -15°C to -25°C in freezer rooms and vaccine freezers.
- Detection of out-of-range storage temperatures so that corrective action can be taken.
- Detection of out-of-range transport temperatures so that corrective action can be taken.

Well-maintained records can be used to assess the quality of the vaccine supply chain, monitor the performance of cold chain equipment over time, and demonstrate compliance with good storage and distribution practices. In primary vaccine stores, continuous temperature monitoring is required; it is recommended in small subnational stores and health facilities.

Regardless of the temperature monitoring device used, temperatures in fixed storage locations should continue to be recorded manually twice a day, seven days a week in large vaccine stores and at least five days a week in smaller subnational vaccine stores and health facilities. Recording temperatures twice daily manually ensures that there is a staff member tasked with monitoring cold chain equipment performance and who can act to resolve issues quickly.

3.2 Estimating required net storage volume of vaccines

Demographic and immunization coverage data for the last year from the EPI five-year strategic plan can be used to calculate the storage volume of vaccines. To estimate the volume, the following information is needed:

- number of target population
- immunization schedule (number of doses of each vaccine needed for immunization)
- target coverage
- packed volume – volume of storage packaging per dose in cubic centimetres (cm^3)
- anticipated vaccine wastage rate – this is used to calculate the wastage factor: wastage factor = 100/(100-wastage rate)
- supply period
- minimum stock.

The above are basic data for calculating the net volume for vaccine storage, which can be determined using two methods:

- Estimated vaccine doses needed/supplied.
- Vaccine volume per fully immunized child (FIC) or full course vaccination (FCV). Usually this method is used when introducing new vaccines.

3.2.1 Calculation based on vaccine doses needed/supplied

This method consists of estimating the needs for vaccines for a given supply period (refer to Module 8: *Vaccine management*). Note that you need a projection of coverage data for a given year (use your five-year plan to extract the target coverage rates).

For each vaccine, multiply the quantity supplied or needed for a given supply period by the packed volume per dose. The result is recorded in either the positive (+2°C to +8°C) temperature or the negative (-15°C to -25°C) temperature column in line with the required storage conditions for each vaccine. The sum for each column will give the net storage volume of vaccines at the respective temperature range.

Table 3.1 Calculation of the net storage volume of vaccines

Vaccines	Presentation (doses/vial)	Quantity of vaccine doses supplied or needed for a supply period (doses)	x	Packed volume* (cm^3/dose)	=	Storage volume according to required temperature of vaccines (cm^3)	
						+2°C to +8°C	-15°C to -20°C
BCG	20		x	1.2	=		
OPV	10		x	2.0	=		
OPV	20		x	1.0	=		
DTP	10		x	3.0	=		
Measles/MR/ MMR	1		x	26.1	=		
Measles/MR/ MMR	2		x	13.1	=		
Measles/MR/ MMR	5		x	5.2	=		
Measles/MR/ MMR	10		x	3.5	=		
TT/dT	10		x	3.0	=		
TT/dT	20		x	2.5	=		
TT	Uniject		x	12.0	=		
HepB	1		x	18.0	=		
HepB	2		x	13.0	=		
HepB	6		x	4.5	=		
HepB	10		x	4.0	=		
HepB	Uniject		x	12.0	=		
Hib	1		x	13.0	=		
Hib	2		x	6.0	=		
Hib	10		x	2.5	=		
Yellow fever	5		x	6.5	=		
Yellow fever	10		x	2.5	=		
Yellow fever	20		x	1.5	=		
DTP-HepB+Hib	2		x	11.0	=		
DTP-HepB+Hib	10		x	7.5	=		
DTP-HepB+Hib	1		x	19.2	=		
DTP-HepB+Hib	10		x	2.6	=		
Men A	10		x	2.6	=		
Pneumococcal	1		x	12.0	=		
Pneumococcal	2		x	4.8	=		
Pneumococcal	4		x	2.4	=		
Rotavirus (2-d)	1		x	17.1	=		
Rotavirus (3-d)	1		x	46.5	=		
HPV	1		x	15	=		
Total			x		=		

* These numbers in this column are indicative and will depend on the manufacturers' packaging.

Estimate your needs based on the vaccine volumes. Remember that diluents for freeze-dried vaccines must be chilled at least one day (24 hours) in advance, before use. Space must be set aside for coolant packs too. You should also foresee any significant increase in immunization activities that would raise vaccine requirements and any other supplies that need to be refrigerated.

Exercise 2

Individual work.
Your national immunization programme has introduced pneumococcal conjugate vaccine (PCV) in single dose vials. Calculate the storage volume of 2 700 000 doses of PCV at the central store that you expect to use in the next six months.
After completing the exercise, check your results with the facilitator.

3.2.2 Calculation based on full course vaccination

This method consists of calculating the net storage volume of vaccine of full course vaccination. The full course vaccination is replacing the previous concept of fully immunized child, as the NIP expands beyond infant vaccinations. Each population grouping by age is analysed to determine the aggregated cold chain needs per inhabitant.[4]

The total net storage volume is obtained by multiplying the volume per full course vaccination and the total number of expected population during the course of the year. Table 3.2 contains information for this purpose.

Table 3.2 Calculation of the storage volume of full course vaccination

Vaccines	Presentation (doses/vial)	Number of doses per target	Target coverage	Packed volume (cm^3/dose)	Wastage		Storage volume (cm^3)
					Wastage rate (%)	Wastage factor	
A	B	C	D	E	F	G	H
Oral polio	10	4	90	2.5	15	1.18	
Yellow fever	10	1	80	3.6	40	1.60	
Measles	10	2	80	3.0	40	1.60	
BCG	20	1	90	1.2	50	2.0	
DTP-HepB-Hib	1	3	90	19.2	5	1.05	
TT	10	2	80	2.5	15	1.18	
PCV-13	1	3	90	12.0	5	1.05	
Rotavirus	1	2	80	17.1	5	1.05	
BCG diluent	20	1	90	1.2	50	2.0	
Measles diluent	10	2	80	4.0	40	1.60	
Yellow fever diluent	10	1	80	3.7	40	1.60	
Net storage volume of full course (cm^3) without OPV and diluents (i.e. primary/subnational levels)							
Net storage volume of full course (cm^3) without diluents (i.e. district level)							
Net storage volume of full course (cm^3) with OPV and diluents (i.e. service delivery level)							
Note: G = 100/(100 - F); H = C x D x E x G Required storage volume in litres = net volume per FCV (in cm^3) x total population							

The volume of FCV corresponds to the vaccines used in the programme with the indicated packaging as shown in Table 3.2. Therefore, in each specific case, for each vaccine used in the NIP calculations should be based on specific package size.

4 WHO Regional Office for Africa (2017). Guide for developing national immunization policies in the WHO African Region (http://www.african-vaccination-week.afro.who.int/wp-content/uploads/2017/03/Guide-for-Developing-Immunization-Policies.pdf).

It is equally important that diluents for vaccines that need reconstitution which may not be refrigerated at national, regional and district levels, are refrigerated at health centre level before their intended use (24 hours in advance). Subsequently, their volume must be taken into account, at the health centre level. If there is not sufficient information on the volume of diluents, this can be taken as equivalent to the volume of the vaccine to be reconstituted.

The wastage rates in Table 3.2 are merely for orientation purposes. They should only be used when data from the field are not available.

The introduction of VVM on vaccine vials as well as implementation of multi-dose vial policy (MDVP) may have great influence on their wastage rates. Countries should ensure monitoring of the vaccine wastage and adjust their estimations accordingly.

Exercise 3

Individual work.
Calculate the net vaccines storage volume of full course vaccination using data from your own immunization programme at different levels.
Discuss your results with your colleagues in the group and with your facilitator.

3.3 Estimating the required cold chain capacity for vaccine storage

The next step is to determine the necessary cold chain capacity to accommodate the vaccine volume we have just calculated. Now we need a multiplying factor or grossing factor that takes into consideration the need for air circulation between vaccine boxes and space between shelves, as well as space for handling. The multiplying factors or grossing factors in Table 3.3 are indicative.

Required gross capacity =
vaccines storage volume x grossing factor

Table 3.3 Multiplying factors or grossing factors

	Cold rooms					Refrigerator/freezer	
Gross factor	5 m^3	10 m^3	20 m^3	30 m^3	40 m^3	Vertical	Chest
	3.2	4.3	5.3	6.1	6.8	2.2–2.5	1.2–1.5

The number of cold rooms/freezers and refrigerators is the ratio of the overall required volume (net vaccine storage volume multiplied by volume factor of corresponding equipment) to gross volume of the selected equipment in question.

Exercise 4

Individual work and plenary presentation.
The health district of Hopelandia has presented the following data:

- total population of 300 000 inhabitants
- children under 12 months = 4%
- immunization target coverage for the next year for children <1 year is 90%.

The required storage volume per FCV is … cm^3 (please do your own calculations).
1. What is the net required vaccines storage volume?
2. What is the number of refrigerators (per type) needed given that:
   - gross volume of a vertical refrigerator is 80 l
   - gross volume of a horizontal refrigerator is 100 l.
3. What will be the supply frequency of the district if the available storage capacity is 200 l?
4. What measures should be taken if the district wishes to receive supplies every three months?

When completed, check your results with the facilitator and be ready to make presentation to the plenary.

Warning

EPI managers should be aware that newer vaccines are much bulkier than the traditional vaccines used in the EPI. The introduction of these new vaccines will require additional cold storage space and may require an expansion of the existing cold chain.

3.4 Selecting cold chain equipment

Once the capacities needed for refrigeration have been determined, the officer in charge of procurement must begin the process of selecting the right cold storage equipment. The WHO PQS device catalogue[5] provides a list of WHO prequalified cold chain equipment for preferential use in immunization programmes. The following should be considered when selecting cold chain equipment:

- cold storage capacity;
- capacity for producing/recycling coolant packs;
- temperature zone – the performance of equipment depends on local conditions: e.g. ambient temperature. In the PQS catalogue, the equipment is categorized for three temperature zones: moderate, temperate and hot, which will help countries to order the appropriate equipment for their zone(s);
- source of energy;
- hold over time; and
- total life cost

If it is not WHO prequalified equipment, ensure it is CFC free. EPI managers should be aware that most domestic equipment is not suitable for storing vaccines.

3.4.1 Cold rooms

Cold/freezer rooms should be used for storing quantities of vaccine over 1.5–2 m^3 of net storage space. A cold room is a complex engineering structure built or assembled on site for storing vaccines and other temperature sensitive products. It requires trained workers for vaccine handling and maintenance. Remember the following points for loading, unloading and maintenance of a cold room:

- Temperature inside the cold room should be mapped[6] to guide vaccine arrangement. Freeze-sensitive vaccines should not be placed in the direct airflow from the cooling units, where they may freeze.
- Vaccines should be placed on shelves (or pallets if required) and not directly on the floor, with space between cartons/boxes for air circulation and handling.
- Continuous temperature monitoring and dial out alarm systems should be installed for each cold/freezer room.

Selecting cold rooms requires specialized knowledge of the product and the supplier. WHO/EPI strongly recommends seeking technical advice to assist in making decisions. (See PQS devices catalogue, Section E001.)

5 http://www.who.int//immunization_standard/vaccine_quality/pqs_prequalified_devices/en

6 Mapping temperatures inside a cold room will consist of drawing a map of the internal temperature in order to identify areas with relatively cold temperatures. Freeze-sensitive vaccines should not be stored in these zones.

3.4.2 Vertical refrigerators

Vertical refrigerators offer easy access to vaccines but must be arranged properly. The vaccines and coolant packs should not be stored in the same compartment!
The volume of each compartment should be calculated separately:

- freezer compartment (coolant packs only)
- vaccine storage compartment.

Ignore "vegetable storage area" in domestic units.

3.4.3 Chest refrigerators

Chest refrigerators should be used with vaccine baskets. Opened vials of liquid vaccine should be kept in a special box in the refrigerator marked "use first" or "returned".

3.4.4 Cold boxes

A cold box is an insulated container with a tight fitting insulated lid and storage capacity above 3.7 l. The cold box is designed for:

- collection or delivery of vaccines
- storage of vaccine (during campaigns, mobile activities, maintenance periods, breakdowns, fast cold chain).

3.4.5 Vaccine carriers

These are insulated containers used for collecting or delivering small quantities of vaccines. The vaccine storage capacity varies between 0.5 (for small carriers) to 3.7 l (large carriers). The temperature inside the cold box and/or vaccine carrier is maintained at the desired level by using coolant packs (cool, conditioned or frozen packs).
Three types of cold/warm life are given on the product datasheets:

- cold life with frozen ice packs
- cool life with cool water packs
- warm life with warm water packs (applicable only in cold climates).

All three tests are carried out with the lid closed. To take account of cold box opening and transport delays, double the estimated cold life requirement. For example, if a proposed activity is estimated to require a 24-hour cold life, select equipment that has at least a 48-hour cold life.

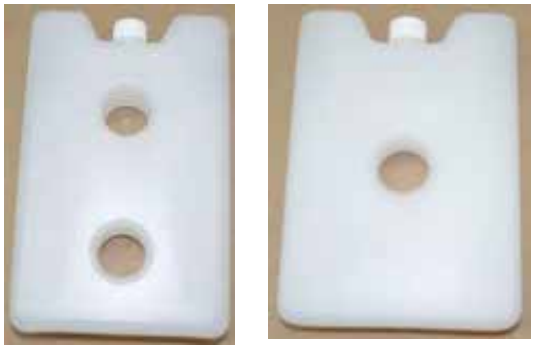
3.4.6 Coolant packs

Coolant packs are rectangular plastic containers to be filled with plain water. They come in different sizes:

- 0.3–0.4 l to be used with vaccine carriers
- 0.4–0.6 l to be used with cold boxes.

Two sets of coolant packs should be provided for each cold box or vaccine carrier – one set to be chilled while the other is being used.

Advanced technologies allow the use of other phase change materials in coolant packs. The use of these phase change materials reduces the risk of freezing vaccines.



3.4.7 International vaccine packaging containers

Vaccines are shipped in packaging containers also called "one-way" containers. These containers are made of polystyrene foam and are quite sturdy, give good protection from heat and cold, and conform to WHO/UNICEF guidelines for international vaccine shipping. The cold life of one-way shipping containers is not as good as those of EPI cold boxes. Their use should be strictly monitored in the programme.

3.4.8 Required surface space for refrigerators

To help the manager to plan the space needed for cold chain equipment, the following indicative information is useful. For every 100 l of vaccines, a floor space of 1.5 m^2 is required. The volume of the room should be no less than 4.5 m^3 for 100 l of vaccines. In addition, the room must be well lit and adequately ventilated. The following must be ensured:

- Compression refrigerators should function on energy sourced from voltage regulators. The equipment must be earthed.
- Absorption refrigerators should not be exposed to direct air flow to avoid oscillation of the flame (this might disturb the heating system of the chimney leading to poor refrigeration).
- Refrigerators must be positioned at least 30 cm from walls to allow for air circulation and to avoid direct heat.
- Refrigerators without a stand must be placed on a stable and vertical palette at least 5 cm above floor level.

In addition to the requirements for installation of cold chain equipment, solar-driven cold chain should take into account the following:

- secured location at the site;
- full exposure of solar panels to the sun (these can be on the ground or mounted on the roof); and
- accessible for regular maintenance, such as cleaning.

4. Managing cold chain equipment

4.1 Inventory of cold chain equipment

In many countries, the MOH may have special inventory forms to record essential data concerning available equipment, including cold chain equipment. The inventory provides up-to-date information on the status of the equipment and helps to improve planning for cold chain.

The objectives of the inventory are:

- To quantify the cold chain equipment by type (active refrigeration equipment, passive devices or insulated containers), transport, energy generator and others.
- To collect data for each piece of equipment (e.g. make, model, age, origin, current location, etc.).
- To report the current status of equipment (functioning, need for maintenance or repairing, etc.).
- To support the gap analysis in terms of capacity and adequacy of cold chain equipment.
- To develop cold chain "rehabilitation" plan.

The cold chain equipment inventory must always be up to date.

4.1.1 Methods for carrying out an inventory

There are at least three methods to carry out cold chain inventory:

Method 1: Regular visits by cold chain technician to the health facilities.

Method 2: Inventory by the programme manager using the inventory form.

Method 3: Collect information during distribution of vaccines to the health facilities.

4.1.2 Data to be collected for inventory

Beside the simple physical count, the inventory acts as a management tool for the immunization programme. The collected data must be of good quality to serve this purpose. The cold chain equipment inventory should contain at least the following data:

- location of the equipment (health centre or clinic, district health centre or hospital, etc.);
- identification of the equipment (type, make, model and serial number);
- age or year of installation of the equipment;
- functional status of equipment (working well, need to be repaired, out of order, not yet installed, etc.);
- source of energy (electricity, solar, gas or kerosene); and
- capacity (storage volume, freezing capacity).

In addition, the following should also be obtained:

- origin or supplier of equipment;
- purchase price; and
- other technical characteristics (e.g. capacity, power consumption, voltage, etc.).

4.1.3 Quality of inventory data

There are three levels of data quality depending on the method of inventory:

- First quality: A qualified technician systematically visits each place and unit where the EPI equipment is located. The technical information on the functioning of the individual equipment is generally accurate and reliable.
- Second quality: The inventory is updated through systematic collection of data from health officers. The exact location, technical characteristics and functional status of the equipment are obtained.
- Third quality: An inventory on equipment provided to EPI by government, various immunization partners/donors. Data on price and origin of the equipment are usually precise, but information on location, date of installation and functional status of the equipment is generally inaccurate.

4.1.4 Frequency of inventory by level of intervention

As mentioned above, it is critical that the cold chain equipment inventory is up to date. It is suggested to update the inventory according to time intervals shown in the Table 4.1.

Table 4.1 Suggested regularity of cold chain inventory by level

Cold chain equipment inventory	National	Provincial	District	Health zone	Health facility
Frequency	1 per year	2 per year	3 per year	4 per year	1 per month

4.2 Maintenance of equipment

4.2.1 Maintenance policy

The main objective of maintenance is to ensure that the cold chain equipment and transport system function well for the implementation of immunization activities. The four common modalities for maintenance are:

- government managed and operated maintenance services
- outsourced maintenance services
- transport and equipment leasing
- public-private partnership (PPP).

Table 4.2 Modalities for maintenance – pros and cons

Modality	Pros	Cons
Government managed and operated maintenance services	• Directly controlled by MOH • Option for EPI maintenance services to be integrated with other health sector maintenance services • Strengthens capacity of MOH to conduct maintenance services	• If standalone service for EPI, generally not a cost-effective solution due to the relatively small quantities and geographically diverse placement of equipment • Constraints of means of transport and displacement allowances to provide prompt maintenance services • Need for regular supervision and quality assurance
Outsourced maintenance services	• Provides good mechanism to control quality and promptness of maintenance services if contract for services is well defined with appropriate performance based incentives and penalties • Maintenance services provided by well experienced and qualified cold chain equipment professionals • Maintenance services can be integrated with other responsibilities and activities of service provider for improved operational and cost efficiency • Effective solution for rehabilitation programmes	• Requires rigorous quality control by MOH • Expensive solution unless part of an integrated programme • Needs a good cash flow to pay for services
Transport and equipment leasing	• Limited experience in the health sector, but experiences with this model have yielded excellent results in terms of economies and programme achievement	• Needs to be part of an integrated services package to be cost effective where transport management, vehicle and refrigerator maintenance are all part of a common programme
Public-private partnership	• A good model if well-structured to ensure that each partner shares the risk of failure • A good model for building quality maintenance services and sharing the financial burden of maintenance • Builds public sector maintenance capacity	• Not sustainable unless private partner continuing presence can be assured • Success dependent upon continuing financial support from both partners unless venture can be oriented towards self-financing through revenue generation

A good maintenance policy should aim to improve maintenance standards and programme cost efficiency. Elements for maintenance policy include:

- Planning maintenance activities which includes responsibilities and resources to carry out the activities.
- Inventory management tools to ensure availability of spare parts and timely replacement of obsolete equipment.
- Appropriate partnership or contracting modalities to ensure accountability of technicians/contractors/partners.

4.2.2 Types of maintenance

Maintenance can be categorized in two groups: **preventive** maintenance and **corrective** maintenance.

Preventive maintenance: Preventive maintenance is the servicing of equipment according to a pre-defined plan and schedule in compliance of established standard operation procedures (SOPs). Servicing is done before equipment failure. Maintenance officers should perform two types of preventive work:

- **Systematic periodic preventive maintenance:** Service task to replace consumable components (wicks replacement, defrosting, cleaning solar panels, topping up batteries, oil/air filter replacement, etc.) at predetermined criteria (age, working hours, transport mileage, etc.).
- **Conditional preventive maintenance:** Service task from a check-up or periodic inspection (oil level alarm, subsequent temperature alarms, etc.). Some examples of periodic preventive maintenance tasks are shown in Table 4.3.

Table 4.3 Periodic preventive maintenance tasks

Key activities	Daily tasks	Weekly tasks	Monthly tasks
Control and monitoring of temperature	Check and record twice a day (morning and afternoon) Check the quality of the flame and adjust for kerosene/gas models	Analyse the curve/trend of the temperature chart Discuss any abnormalities in the expected pattern with your supervisors	Analyse the curve /check alarm/ trend of the temperature chart Discuss any abnormalities in the expected pattern with your supervisors
Arrangement of vaccines, diluents and coolant packs	Make sure that there is no ice and that coolant packs are loaded according to national guidelines Application of earliest expiry first out (EEFO)	Remove expired stock including vaccines with VVMs beyond the discard point Ensure replacement of stocks	
General maintenance	Clean, dry and store cold boxes and vaccine carriers used during the day Check the quality of the flame and adjust for kerosene/gas models Check the functionality charge regulator for the solar refrigerator with battery Adjust the thermostat if there is a variation in temperature	Check the availability of kerosene or gas Check if the refrigerator/ freezer need to be defrosted Check the sealing ring and hinges on the door Clean and wipe off the dust outside the refrigerator/freezer	Check and clean the solar panels, compressor, condenser, etc. Verify the level of the refrigerator that it is ok Check the level of battery water for the solar refrigerator Ensure that the solar panel is not obstructed by any object to prevent the shadow
Reporting	Report to the supervisor any problem observed in cold chain equipment In case of cold chain equipment failure and/or long interruption of electricity, act according to the contingency plan		Complete the monthly reporting forms according to the instructions and submit them to your supervisor

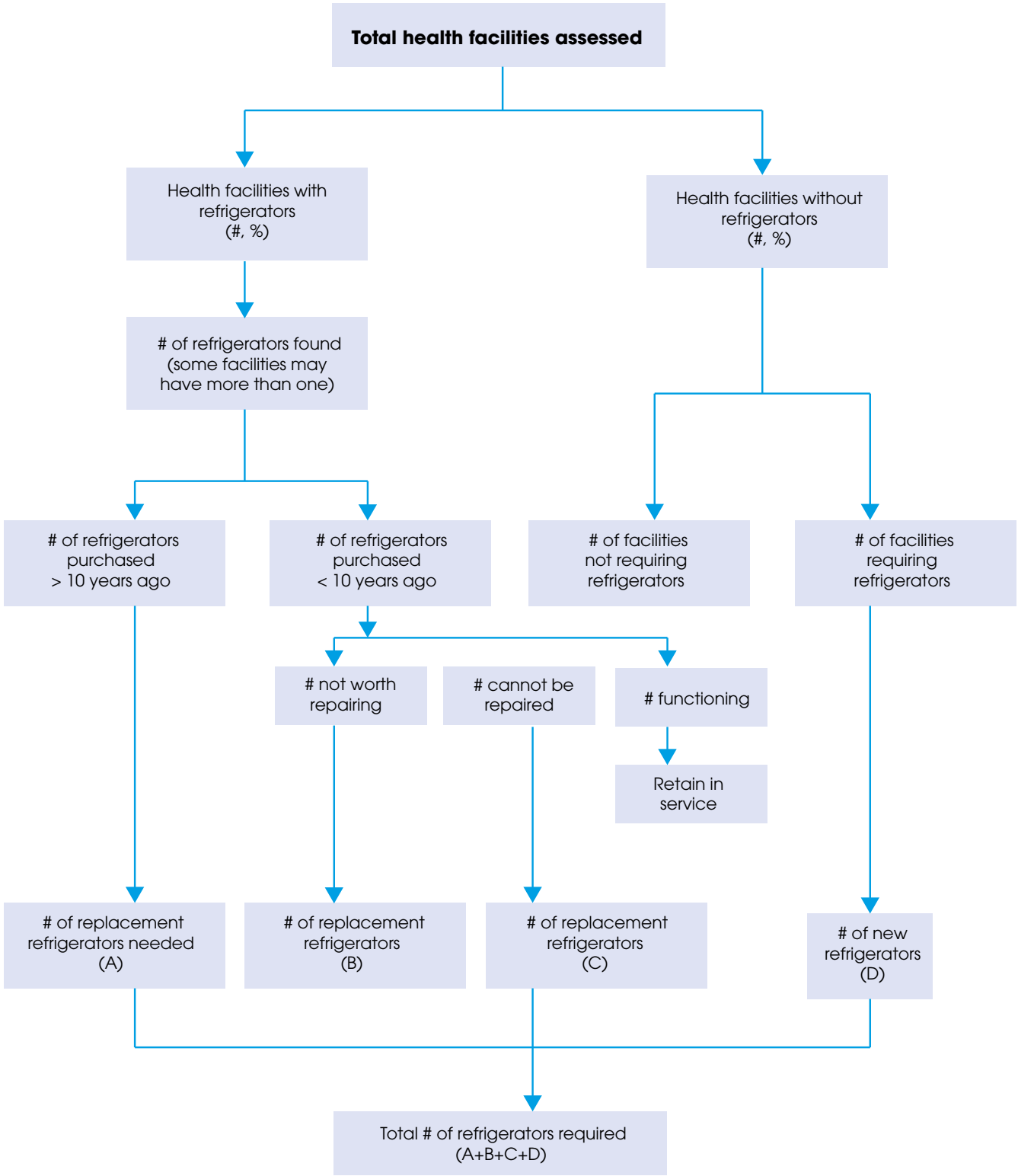
Table 4.4 Repair responsibilities at different levels

Refrigerators requiring spare parts	Who is responsible for repairing?			
	Staff at health centre	Local/district technician	Regional technician	Central workshop
Kerosene and electric refrigerator	Lamp glass Sealing ring Door gasket Wick Brush to clean the chimney	Burner Heating element Door hinges Wick Glass for kerosene Doors	Doors Heating element Door hinges Wick Glass for kerosene Doors	Cooling unit Heating element Door hinges Glass for kerosene Doors
Gas and electric refrigerator		Gas hose Door gasket Heating element Gas injector	Thermostat Gas injector Hinges Heating element	Thermostat Gas injector Hinges Heating element
Electric refrigerator (compression)	Fuse	Thermostat Door hinges	Compressor Starting device Overload cut-off Thermostat	Compressor Starting device Overload cut-off Thermostat
Solar refrigerator	Fuse Distilled water (battery)	Door rubber and hinges	Power regulator Thermostat Compressor Cables, battery, fuse	Compressor Condenser Solar panels, fuse

With good planning and maintenance, it is possible to avoid unexpected failures of the cold chain equipment. As a mid-level manager, you should aim to update the inventory every year and plan both the replacement of old equipment and the establishment of new equipment. Figure 4.1 shows how the inventory information can be presented in order to calculate the total equipment requirements. This clear presentation of data will provide important evidence to the national level managers of the need for new equipment. Plans for the supply of cold chain equipment should be based upon the following key factors:

- Cold chain equipment is supplied as a first priority to eliminate the deficit of storage capacity at primary, intermediate and lowest distribution levels.
- New equipment is supplied to meet the additional need for storage capacity if and when additional new vaccines are added.
- New equipment is supplied to replace irreparable failures of installed equipment over a five-year period.
- Energy source and sustainable strategies for equipment supply.

Figure 4.1 Flowchart overview of refrigerator requirements



Corrective maintenance: Corrective maintenance is unanticipated and should be minimal if preventive maintenance is effective. The corrective maintenance can be:

- Temporary repair – to render the equipment functional until lasting permanent repair or supply of the spare part can be performed.
- Permanent repair – definitive repair.

The manager must have an updated inventory showing the exact location of all the equipment, so that they can provide the maintenance technician with the right information at any time.

4.2.3 Replacement of ageing or obsolete equipment

Equipment, whether fixed or mobile, reaches a point in its operational life when it is no longer economically viable to maintain it, and therefore should be disposed of.

If any equipment malfunctions or fails completely, a decision should be made as to whether to replace or repair it. This can be a difficult decision; especially if the equipment has failed earlier than expected (a cold chain refrigerator is generally considered to have a lifespan of at least 10 years). The following statement is a practical rule of thumb to help make the decision on whether to repair or replace: "when the cumulative repair cost is equal to, or higher than, the depreciated value of the equipment, the recommended practice is to replace rather than repair it".
(The depreciated value = the original value of equipment minus loss of value due to wear and tear, ageing, or obsolescence.)

Figure 4.2 illustrates how to put this rule into practice.

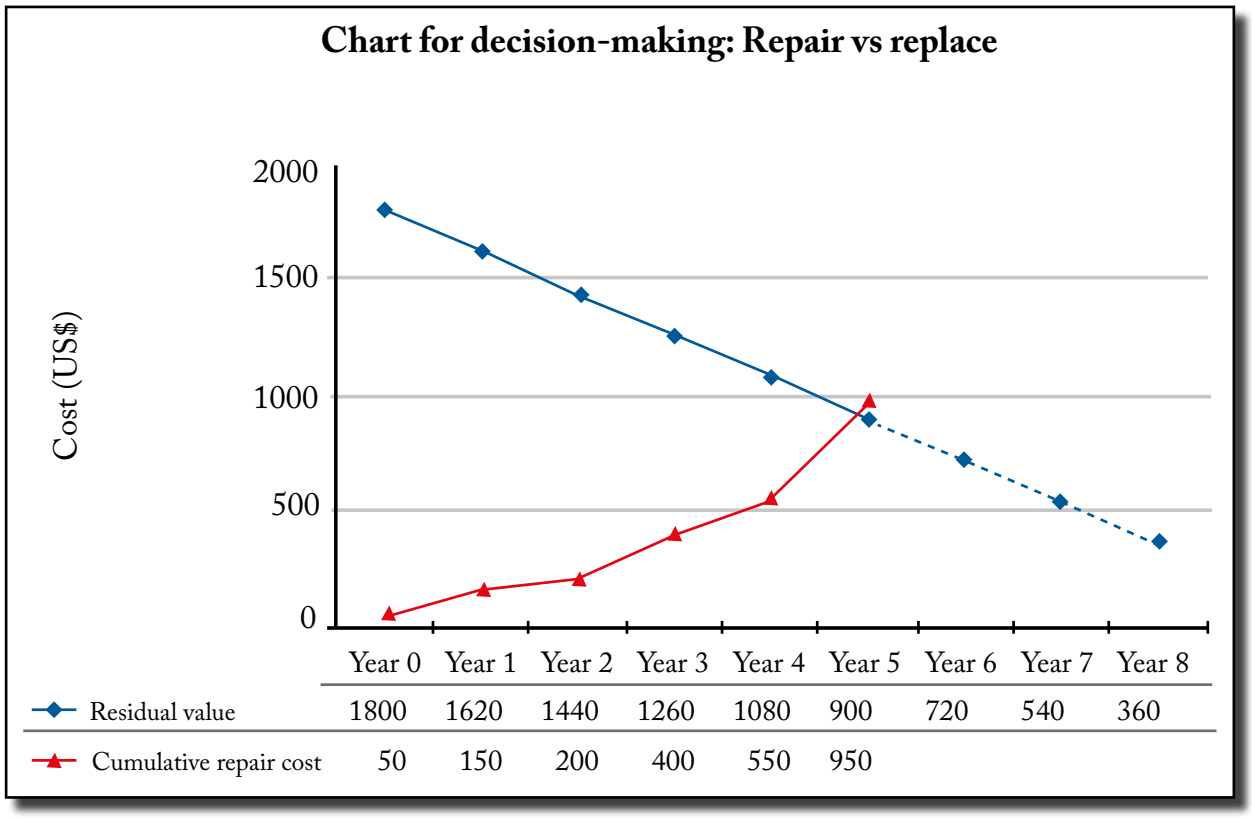
EPI managers should work closely with cold chain managers to develop a replacement plan. The following principles have to be considered for a rehabilitation plan:

- Absorption refrigerators and freezers must be replaced.
- Refrigerators and freezers over 10 years old should be replaced.
- New cold chain equipment should be selected based on its comparative advantages and total cost of ownership.
- Any new cold storage equipment (refrigerator or cold room) must be procured bundled with the appropriate temperature monitoring system and energy stabilizer (where required).
- All health facilities must provide EPI services and to do so they must be equipped with EPI standard refrigerator and/or cold box/vaccine carrier.
- Solar powered units should be introduced gradually where there is no reliable/adequate electricity supply.
- National, regional and district logisticians and technicians must be trained on cold chain equipment maintenance and a workshop established with adapted tools and spare parts for repair.

Monitoring tools and equipment must be introduced gradually along with new cold chain equipment. Technical staff should be trained in their use. Regular updating of inventories is also a priority in the rehabilitation plan.

To ensure durability of recently rehabilitated cold chain, communities and health development committees (at district or health centre level), which are beneficiaries of donated equipment, should be encouraged to share their maintenance costs.

Figure 4.2 Example of equipment replacement point



5. Planning for the cold chain

5.1 Preparing the cold chain annual plan

The cold chain manager should prepare a cold chain annual plan, based on the EPI five-year strategic plan (cMYP) and immunization services plan of action. The format of this plan should follow the general principles discussed in Module 4: *Planning immunization activities*.

The plan should have the following sections:
1. **Introduction**/background.
2. **Situation analysis** based on the latest inventory results of the cold chain equipment and/or EVM assessment.
3. **Objectives** of the plan should be based on overall EPI objectives, specifying the role of cold chain in achieving them (e.g. maintaining good performance of the cold chain to assure high quality of vaccines at all times).
4. **Strategies** where various cold chain options should be discussed (slow, fast cold chain, type of maintenance modality, etc.). Vaccine and injection material distribution systems should be described in conjunction with two systems – pull or push.
5. **Targets** should be measurable for effective monitoring. The following example may help to formulate a target: "By the end of the planning period, xx% of service delivery points will have cold chain equipment with vaccine storage capacity for at least the established maximum stock level".
6. **Activities** including a wide range of actions, summarized as follows:

- evaluation of annual vaccine and supply needs and vaccine volume requirements
- inventory of the cold chain equipment
- acquisition of new cold chain equipment
- provision of repair, emergency and rehabilitation services
- in-service or formal training of health personnel in cold chain and logistics
- regular (monthly/quarterly/semi-annually) supportive supervision and feedback
- regular reporting on cold chain performance through monthly/quarterly reports
- other activities as per specific needs of the programme.
- The timeline and responsibilities should be indicated in the plan.

7. **Budgetary estimations** where all activities in the plan should be costed and the budget included in the plan to facilitate resources allocation or mobilization (refer to Module 6: *Immunization financing*).
8. **Monitoring of the plan** should include a set of monitoring indicators that show achievements against set targets (see Annex 1 for a list of selected cold chain monitoring indicators).

5.2 Preparing the cold chain emergency plan

Emergency plans should be made in anticipation of a crisis during operation of the cold chain. The most common emergency situations in a cold chain include:

- breakdown of refrigerators, freezers or cold rooms
- shortages of fuel or electricity power cuts
- freezing of freeze-sensitive liquid vaccines
- change of VVM colour (at discard point and beyond)
- breakdown/non-availability of vehicle
- sudden or unplanned supply of large quantities of vaccine to a facility with limited storage capacity
- absence of health centre staff (e.g. due to illness)
- destruction of the vaccine store due to natural disasters or poor maintenance of the building.

Any of these situations could threaten the immunization programme. Thus, emergency planning can reduce potential damage these crises can cause. One way of anticipating emergencies in the cold chain is to identify those situations that are likely to happen (forecasting). Each time ask the following questions ("the three A's"):

Is there **another** solution?
Is it **adequate** for the situation?
Is the solution **affordable/accessible?**

Answering these questions before an emergency occurs will help in responding to a real emergency. For example:
1. When a refrigerator breaks down what measures would be taken?
The starting point is the contingency plan by answering the following questions:

- Is there another available refrigerator nearby, ready to be used? (Is there **another** solution?)

- Is the refrigerator big enough to accommodate all vaccines with satisfactory temperature control system? (Is it **adequate** for the circumstances?)
- Can we pay the transportation cost? (Is it **affordable**?)

2. If the person in charge of the refrigerator is absent, what measures would be taken?

The contingency plan should answer the following questions:

- Is there a replacement person? (Is there **another** solution?)
- Is the replacement person capable of carrying out all the required tasks? (Is it **adequate** for the situation?)
- Is the replacement person available to carry out the tasks? (Is he/**she accessible**?)

Tip

Display the contingency plan with contacts of persons concerned

PERSON IN CHARGE OF THE VACCINES

Name.....

Name of the person for replacement.....

Contact numbers (including mobile numbers).....

IN CASE OF EMERGENCY TRANSFER VACCINES TO:

Exact location of the refrigerator.....

In a cold chain emergency, personnel from the service delivery point must report the problem to their immediate supervisor:

- **Describe the problem:**
  - What is the highest temperature each type of vaccine has been exposed to?
  - How much time has passed between the breakdown of the cold chain and the time at which the highest or lowest temperatures have been reached?
  - How many doses of each vaccine have been affected?
  - What are their expiry dates?
  - What is the temperature reading from the cold chain control indicators?
- **Determine the cause of the problem:**
  - Use the available data and investigate further to identify the possible causes.
  - Refer to the contingency plan for information on specific action, location, designated person's name and other details.
- **Refer to the contingency plan**
- **Take measures to resolve the problem and prevent its re-occurrence:**
  - Send this information to your supervisor immediately so they can decide whether the affected vaccines should be used, checked or disposed of.
  - Send the same information to the cold chain technician to fix the equipment.
  - Discuss with the service delivery staff how to solve the current problem and prevent its reoccurrence.

(Refer to Module 1: *A problem-solving approach to immunization services management*.)

Exercise 5

Individual work.

Following the procedure for the three A's, list the main questions you need to answer to put a contingency plan in place, if:

- A refrigerator breaks down.
- The person in charge of the refrigerator is away.

5.3 Preparing standard operating procedures

WHO has published a series of standard operating procedures (SOPs) specifically for EVM.[7] The WHO guidelines on SOPs also provide instructions to write or revise SOPs. They must:

- Provide personnel with all the health, safety, environmental and operational information needed to perform a task correctly.
- Ensure that operations are performed consistently in order to maintain quality control.
- Ensure that processes continue uninterrupted and are completed within the required timeframe.
- Ensure that no failures occur that could harm anyone.
- Ensure that approved activities are followed in compliance with policies, procedures and/or legislation.
- Serve as a training document, e.g. for a new stores assistant or vaccinator.
- Serve as a historical record of the how, why and at what step in an existing process the incident happened.
- Serve as an explanation of steps in a process so they can be reviewed in the event of an incident investigation.
- Be formally authorized, distributed, implemented and maintained.
- **Responsibilities:** Describe and list the people (preferably by job title) responsible for performing each of the activities listed in the SOPs. In some cases, the tasks in the SOPs will be carried out by a single staff member. In other cases the tasks will be carried out by more than one person.
- **Materials and equipment:** Describe any special materials or equipment that will be needed to perform the specific procedure. For example: a freezer or freezing compartment is needed to conduct the shake test and warm clothing is needed to work in a cold room or freezer room.

7 http://www.who.int/immunization/programmes_systems/supply_chain/evm/en/index2.html


STOP

6. Monitoring and supervising the cold chain

6.1 Cold chain monitoring

Monitoring the cold chain is a key activity for the immunization manager. The monitoring will include the availability, capacity and reliability of cold chain equipment as well as the programme performance. Annexes 1–3 will help cold chain staff and supervisors in the monitoring process.

The following aspects are important in monitoring the cold chain.

Adequacy of the cold chain
A cold chain is considered adequate when the following criteria are met:

- Equipment meets the required standards for storage and freezing/cooling capacities.
- Personnel are trained to operate the equipment in an optimal manner.

The manager should be able to assess the adequacy of the cold chain using the following indicators:

- Percentage of cold chain equipment meeting standards (including environmentally friendliness).
- Number of storage/service points with adequate cold chain capacity.
- Number of storage/service points with cold chain contingency plan.
- Number storage/service points with at least one staff trained on cold chain management.

Reliability of the cold chain
A cold chain is considered reliable if there is no interruption and the temperature is maintained within the recommended ranges. The reliability of the cold chain is achieved with good maintenance. The following indicators are suggested to monitor the reliability of the cold chain:

- Existence of a contingency cold chain plan.
- Number of temperature alarms per month (see Annex 3 for an example).
- Number of days of cold chain breakdown (lack of fuel, spare parts not available, need for repair) per month.
- Proportion of vaccine discarded over total quantity in stock per month due to temperature deviations.

Cold chain maintenance
The manager will follow up on the following indicators:

- Number of days waiting for maintenance or repairing services.
- Number of storage/service points that can do the preventive maintenance.
- Total costs of maintenance per storage/service points and cold chain equipment considering:
  - cost of spare parts
  - cost of labour.

6.2 Reporting

All storage/service points should report the cold chain performance on a monthly basis. The managers should analyse reports received and submit a consolidated report to immediate supervisors for validation. Feedback should be given to report providers on any decisions or action taken as appropriate.

6.3 Motivation

To keep the cold chain working optimally, personnel should be motivated, problems be understood and resolved and managers focus on the aspects of the cold chain for which they are directly responsible. Motivation should include encouragement for good performance and regular feedback.

6.3.1 Motivation and problem-solving – a stepwise approach

Before you can solve a problem, you must first understand its causes. The following is a summary of the steps to take in solving cold chain problems.

Step 1: Describe the problem

To describe the problem well, ask yourself the following questions:
What tasks have not been done properly?
Where is the problem?
Does the problem concern all health staff or only some of them?
At what time and with what frequency does the problem occur?
How long has the problem been in place?

Step 2: Identify the possible causes of the problem

To identify the causes of the problems, ask yourself the following questions:
Does the health worker have the required skills or knowledge?
Is the health worker motivated?
Has the health worker been assigned tasks necessary to ensure proper functioning of the cold chain?
Are there obstacles to the good functioning of the cold chain (e.g. frequent electricity cuts)?

Step 3: Find an appropriate solution

A problem can be solved in several ways:
Choose a solution that addresses the exact cause of the problem.
Consider searching additional resources. For example, private businesses can help you get funds for needed supplies, or volunteers recruited from the community can help carry out certain repair tasks.
Your solution should fulfil two conditions:

- It must solve the immediate problem.
- It must prevent the problem from happening again!

Step 4: Take corrective measures

Cold chain problems must be solved quickly; otherwise vaccines might be at risk with negative impacts on the immunization programme.

Using the stepwise approach outlined above, consider the following two examples of problems encountered in cold chain operational management and illustrations of possible solutions.

Problem 1

Describe the problem	Identify possible causes	Find possible solutions
The cold chain manager/ officer is absent. During their absence, a vaccine consignment arrives. Another staff member freezes the vaccine DTP-HepB-Hib and TT by placing them in the freezer.	1. No emergency plan has been prepared to provide advice in the absence of the cold chain officer.	1a) Prepare or update a contingency plan to cover situations when officers are absent. 1b) Remove damaged vaccine from the stock.
	2. Other staff members do not have the skills needed to perform tasks essential to the proper functioning of the cold chain.	2a) Train other staff in basic cold chain tasks (e.g. placement of vaccines in refrigerator). 2b) Make sure that the staff regularly perform these tasks. 2c) Improve supportive supervision so they can perform these tasks when necessary.
	3. Other staff members are not motivated to carry out tasks needed for the smooth running of the cold chain.	3a) Explain the importance to perform these tasks properly. 3b) Improve supervision and reward good work.
	4. No other staff member has been assigned to perform tasks when the cold chain officer is absent.	4a) Assign other trained staff to implement the emergency plan. 4b) Arrange for them to practise these tasks periodically.

All possible causes of a problem should be considered. If the service delivery supervisor does not consider all possible causes, there is risk of:

- Solving only one part of the problem (for example, preparing a contingency plan without having trained the health staff and given them clear instructions on their tasks in an emergency).
- Choosing a solution that does not solve the problem (for example, punishing the officer who froze the vaccine that is sensitive to freezing, without ensuring that the problem does not re-occur).

Problem 2

Describe the problem	Identify possible causes	Find possible solutions
The refrigerator at the health centre has broken down. The technician is called. While waiting for their arrival, the cold chain officer stores the vaccines in their office. Thus, a month's stock of polio vaccine is destroyed because it has stayed for a long time at ambient temperature and the VVM has reached discard point.	1. No emergency plan has been developed for refrigerator breakdowns.	1a) Develop a contingency plan for refrigerator breakdowns. 1b) Report the late arrival of the technician to the maintenance supervisor.
	2. The officer thought vaccines could be kept at the ambient temperature because of the VVM.	2. Train the staff to store vaccines properly.
	3. The cold chain officer lacked the motivation to find a suitable facility to store vaccines.	3. Explain why it is important to keep vaccines cold, improve supervision and reward for good work.
	4. No cold box was available at the facility.	4. Order/obtain a cold box or find another way to keep vaccines cold during breakdowns (other refrigerator at the facility or nearby; also try public or private sources).

This second example also shows that it is important to identify the causes of the problem. If the supervisor does not consider all possible causes, they risk finding only a partial solution. For example, they can decide that the problem is due to the cold boxes, overlooking the fact that the health worker was not qualified or motivated.

Exercise 6 – Identification of problems and solutions

For all groups.
In this exercise, you should identify the causes of the existing cold chain problems and look for possible solutions.

The following job cards describe two cold chain problems. Complete the columns, considering all possible causes of each problem and the solutions to tackle the causes. For the third job card, think of a cold chain problem that you have encountered in your work. Identify its causes and the corresponding solutions. Indicate long-term solutions that will prevent such problems occurring in the future.

Job card 1

Describe the problem	Identify possible causes	Find possible solutions
The district storekeeper distributes vaccines to the health worker who comes to collect the monthly supply for the service delivery. However, since the district vaccine stock is low, the storekeeper picks up half the quantity requested and gives it to the health worker.		

Job card 2

Describe the problem	Identify possible causes	Find possible solutions
The health worker is preparing for an outreach session. There is only one chilled water pack in the refrigerator. They place this chilled water pack in the vaccine carrier before loading it with vaccines. At the immunization post they vaccinate children and women, although the vaccines have not been adequately stored in the vaccine carrier.		

Job card 3
Use this card to describe a problem that you have recently encountered in your work. Identify the possible causes and solutions to this problem.

Describe the problem	Identify possible causes	Find possible solutions

When you have finished this exercise, prepare your presentation to the plenary.

6.4 Supervision

Supervision generally is part of a capacity-building strategy. The manager's cold chain supervision activities consist in identifying the weaknesses of cold chain management and strengthening the technical competencies of health officers in order to sustain, monitor and maintain the cold chain. Supervision is necessary to ensure adequate control of materials and maintenance operations undertaken by technicians from either the public or private sector. For proper supervision, a well-prepared plan is essential. This plan should include:

- the frequency of supervision visits for each level;
- the composition of the supervision teams and their scheduled visits;
- estimated need for vehicles, fuel and personnel; and
- a budget to cover the above expenditures.

Table 6.1 Tasks of the cold chain officer/supervisor/EPI manager to ensure proper functioning of the cold chain

Frequency of tasks	Tasks of the cold chain officer/health staff	Tasks of supervisor/EPI manager
Daily tasks	1. Monitor functioning of the cold chain 2. Record temperature of each cold chain equipment twice daily 3. Check that vaccines are arranged properly in the refrigerator 4. Check coolant packs (frozen in freezer or cold in refrigerator)	1. Respond to enquiries and give technical advice to the cold chain officer/health staff 2. Perform on the job training
Weekly tasks	1. Arrange talks on cold chain with other colleagues in the team 2. Conduct preventive maintenance 3. Report any irregularities in cold chain 4. Remove any damaged/expired vaccine	1. Respond to enquiries and give technical advice to the cold chain officer/health staff 2. Check if vaccines are properly handled and placed in refrigerator/freezer 3. Check if temperature monitors are in order
Monthly tasks	1. Prepare and send monthly report 2. Replenish vaccine stock 3. Conduct preventive maintenance	1. Prepare monthly report 2. Identify problems and solve them, using problem-solving approach 3. Organize meeting/seminars for cold chain officers 4. Prepare/update monthly plan
Quarterly tasks	1. Prepare and send quarterly report 2. Replenish vaccine stock 3. Carry out preventive maintenance 4. Conduct regular supportive supervision	1. Prepare quarterly plan 2. Prepare quarterly report 3. Conduct quarterly supervisory visits 4. Check if the facilities have received adequate vaccines and supplies 5. Check if vaccines are handled and stored properly
Annual and other periodic tasks	1. Prepare and send annual report 2. Conduct cold chain inventory 3. Carry out preventive maintenance 4. Propose replacement of cold chain equipment 5. Organize short-term training of health workers	1. Receive and analyse annual reports 2. Prepare an annual plan 3. Prepare a consolidated annual report for higher level managers 4. Exchange best practices within area 5. Conduct an emergency plan 6. Conduct supervision visits 7. Conduct/participate in cold chain review

Recommended reading

WHO (2008). Implementing the Reaching Every District approach: A guide for district health management teams. Regional Office for Africa: World Health Organization. Available at: http://www.who.int/immunization/programmes_systems/service_delivery/AFRO-RED_Aug2008.pdf (accessed 5 December 2016).

WHO (2013). Global Vaccine Action Plan 2011–2020. Geneva: World Health Organization. Available at: http://www.who.int/immunization/global_vaccine_action_plan/GVAP_doc_2011_2020/en/ (accessed 5 December 2016).

WHO (2014). WHO policy statement: Multi-dose vial policy (MDVP). Handling of multi-dose vaccine vials after opening. WHO/V&B/14.07. Geneva: World Health Organization.

WHO (2015). Regional Strategic Plan for Immunization 2014–2020. Regional Office for Africa: World Health Organization. Available at: https://www.aho.afro.who.int/en/ahm/issue/19/reports/regional-strategic-plan-immunization-2014–2020 (accessed 5 December 2016).

WHO (2015). WHO vaccine management handbook. Module VMH-E2-01.1. How to monitor temperatures in the vaccine supply chain. WHO/IVB/15.04. Geneva: World Health Organization.

WHO (2015). WHO vaccine management handbook. Module VMH-E7-02.1. How to use passive containers and coolant-packs for vaccine transport and outreach operations. WHO/IVB/15.03. Geneva: World Health Organization.

WHO (2017). Performance, Quality, Safety (PQS) Catalogue. Geneva: World Health Organization. http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/ (accessed 12 May 2017).

WHO (2017). Mid-level management course for EPI managers. Module 1: A problem-solving approach to immunization services management. Brazzaville: World Health Organization Regional Office for Africa.

WHO (2017). Mid-level management course for EPI managers. Module 4: Planning immunization activities. Brazzaville: World Health Organization Regional Office for Africa.

Websites

WHO – Immunization, Vaccines and Biologicals (Effective Vaccine Management Initiative): http://www.who.int/immunization/programmes_systems/supply_chain/evm/en/

WHO – Immunization, Vaccines and Biologicals (Vaccine management and logistics support): http://www.who.int/immunization/programmes_systems/supply_chain/resources/tools/en/

WHO – Immunization, Vaccines and Biologicals (Immunization training resources): http://www.who.int/immunization/documents/training/en/

Annex 1: Selected cold chain monitoring indicators

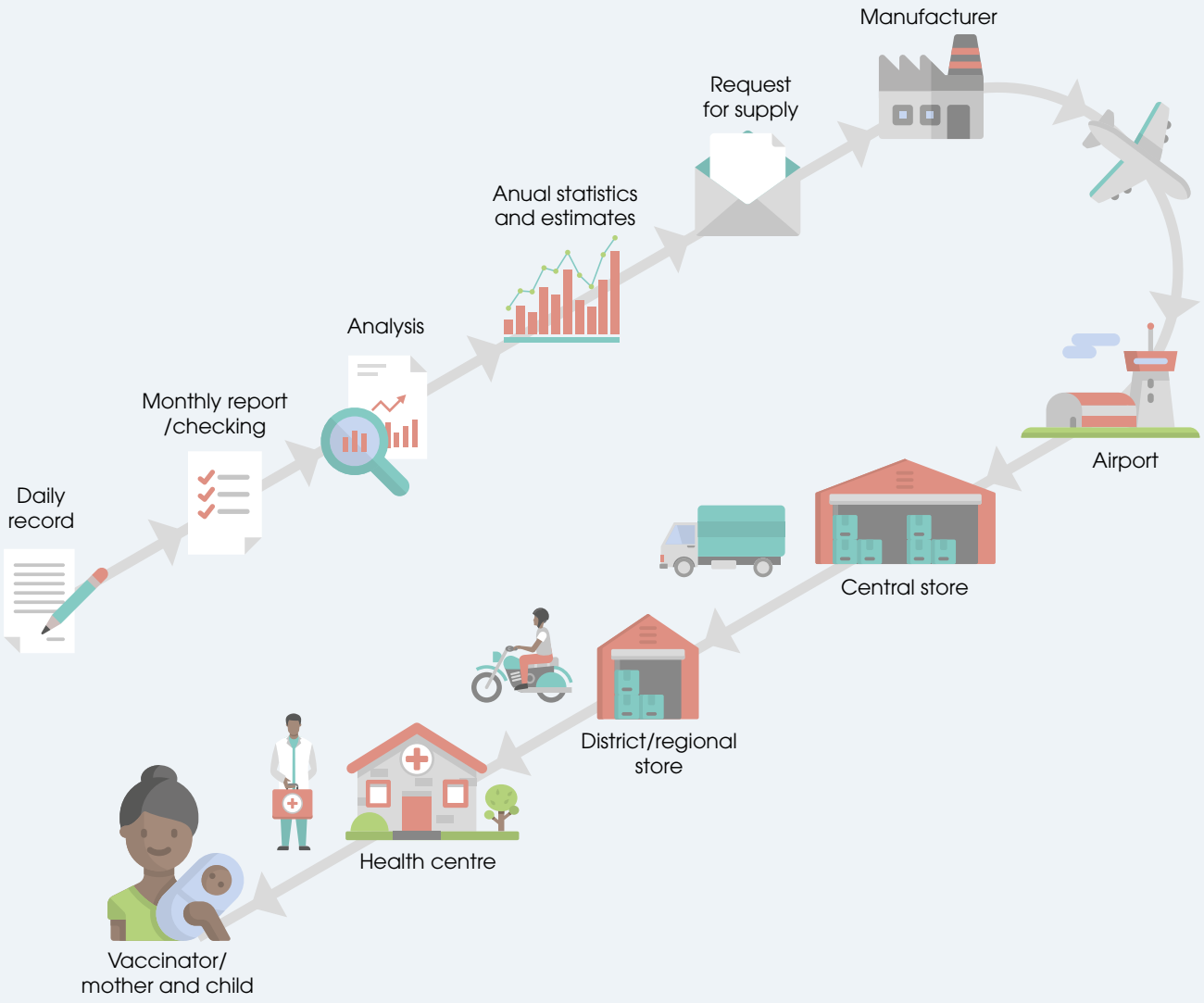
- Number of days in a given period the temperature was recorded correctly: twice daily on the temperature chart.
- Number of days the temperature was outside the recommended range.
- Number of days the refrigerators was broken down:
  - due to lack of fuel
  - due to lack of spare parts
  - due to absence of repair technician.
- Time lag before corrective measures were taken.
- Amount of OPV discarded after VVM reached discard point.
- Amount of frozen freeze-sensitive vaccines (e.g. DPT, HepB).
- Amount of vaccines discarded due to reaching expiry date.
- The total cost of discarded vaccines due to above reasons.
- Cold chain operational plan in place and in use.
- Cold chain maintenance plan in place and in use.
- Cold chain emergency plan in place.
- Cold chain equipment inventory available and consistent with their physical presence.
- Regular reporting on cold chain in place.
- National cold chain officer trained/re-trained during the last three years.
- Staff assigned to cold chain at health facility level trained in cold chain basics:
  - number of assigned staff to cold chain
  - number trained.

Annex 2: Vaccine cold chain monitor

Vaccine control indicators

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

The temperature of the entire cold chain from central store to point of use of vaccines should be monitored continuously. The diagram below shows a typical temperature monitoring and vaccine supply chain.



Transport of vaccines from manufacturer to central cold room

Irreversible electronic temperature indicators show if the vaccine has been exposed to temperatures beyond assigned alarm settings. They consist of an electronic temperature measuring circuit with associated LCD-display. As long as the temperature is within the allowed range, the OK sign is shown on the display. If the indicator is exposed to an out-of-range temperature the ALARM sign appears on the display.

Information displayed includes:
1. Actual elapsed transport time with ALARM sign and violated alarm condition.
2. Actual elapsed transport time since start with OK sign.
3. Extreme temperatures.
4. Exact time from START until the alarm occurrence.

WHO PQS Ref E006/002

WHO PQS Ref E006/010

Cold room monitoring and alarm system

Monitoring cold rooms and stores with multiple vaccine refrigerators (six or more). Multichannel continuous temperature monitoring systems with provision for permanent digital data storage and data backup along with automatic call-out alarm systems are required. Each cold room should be mapped when heavily stocked and when lightly stocked to determine hot and cold spots. A minimum of four temperature sensing probes should be installed in each cold room (more for cold rooms larger than 40 m^3) to monitor vaccine temperatures. Automatic dial-out alarms should be fitted which call out to pre-programmed fixed or mobile communication networks when adjustable alarm thresholds are reached.

Multilog: For temperature monitoring in cold/freezer room

- 8, 12 and 16 channel models available.
- Auto-dialler alarm option recommended.
- Range: -30°C to +70°C.
- Each Multilog needs to be connected to a dedicated desktop PC with UPS.
- Each Multilog to be supplied with sensor cables for each channel. Cable length options, 25 m, 50 m, 100 m, 200 m.
- Typically 6 to 8 channels/cold room required.

Supplier: Remonsys Ltd: http://www.remonsys.com; email: lewis@autolog.u.net.com; www.autolog.u.net.com

Vaccine refrigerator continuous temperature monitoring and alarm system

The continuous monitoring of vaccine refrigerators is required via an irreversible temperature indicator for vaccine refrigerators that shows if a vaccine has been exposed to temperatures beyond the assigned alarm settings. As long as the temperature is within the allowed range, the OK sign is shown on the display. If the indicator is exposed to an out-of-range temperature the ALARM sign appears on the display. The device shows the actual temperature and all alarm violations over the previous 30 days (on a rolling basis), the daily minimum and maximum temperature of the last 30 days, and the time duration of any violation. The useful life of such devices is approximately two years.

WHO PQS Ref E006/03: Fridge tag

WHO PQS Ref E006/13: Log tag

Digital freeze indicators used in cold boxes and vaccine carriers when freeze-sensitive vaccines are transported

An irreversible temperature indicator that shows if a product, such as vaccine, has been exposed to freezing temperatures. It consists of an electronic temperature measuring circuit with associated LCD-display. If the indicator is exposed to a temperature below -0.5°C ±0.5°C for more than 60 mins ±3 mins the display will change from "good"to "alarm" status. A small blinking dot in the righthand corner of the LED display indicates that the device is functioning.

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

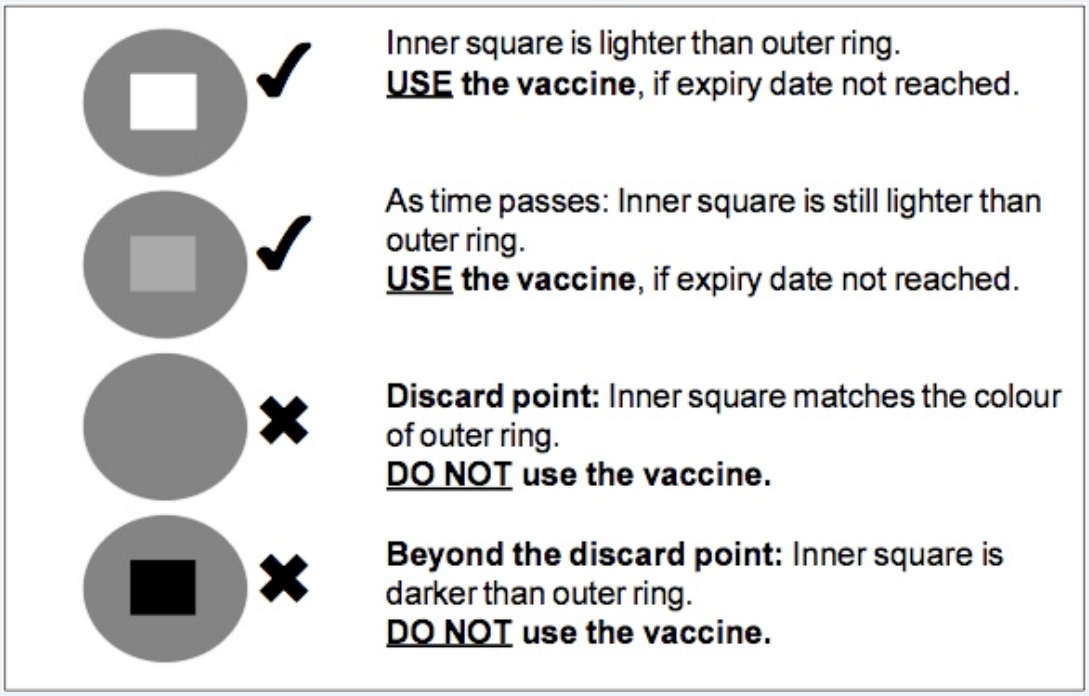
- a thermometer
- a temperature chart taped to the outside of each refrigerator used for vaccine storage.

WHO PQS Ref E006/03: Fridge tag

WHO PQS Ref E006/13: Log tag

Vaccine vial monitors

Vaccine vial monitors are vaccine control indicators mounted on vaccine vials at the point of manufacture. The monitor is time/temperature sensitive and indicates when a vial should no longer be used. Vaccines of different types and from different manufacturing sources may be fitted with different types of VVM. The colour of the inner square of a VVM progresses through four stages as shown below.



Annex 3: Refrigerator temperature monitoring chart

DAILY TEMPERATURE SHEET

Health Facility:..... Month/Year:.....

Refrigerator (Model):.....

Date		TEMPERATURE (°C)				#ALARMS		IMMUNIZATION ACTIVITIES INTERRUPTED				
		Tick the appropriate box						If Yes, cross the box indicating appropriate reason				
		< 0	0 - 1	2 - 8	> 8	Low T	High T	Lack vaccines	Energy failure	Breakdown	Lack transport	Other (specify)
1	AM											
	PM											
2	AM											
	PM											
3	AM											
	PM											
4	AM											
	PM											
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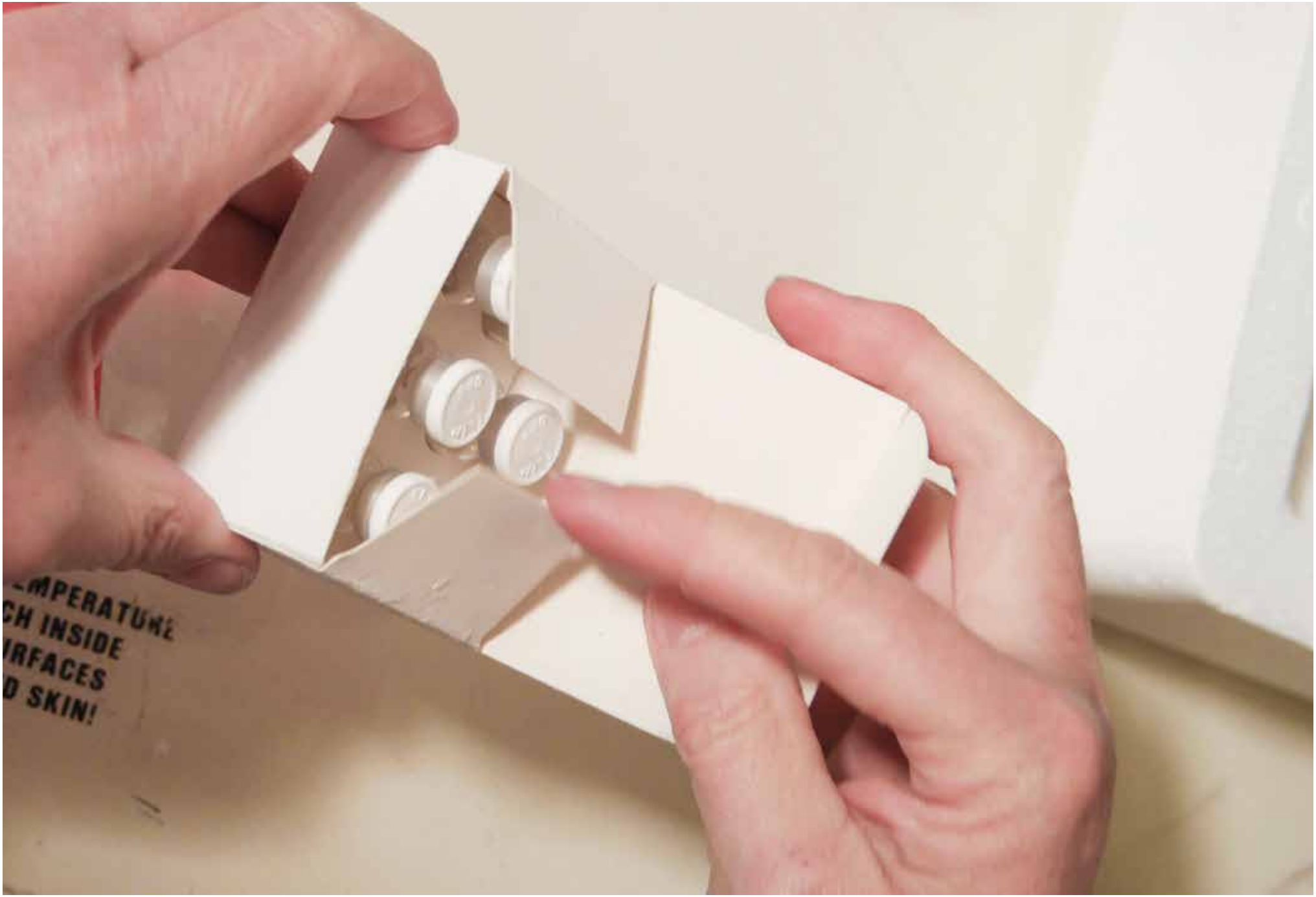
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ale de la Santé

World Health Organization

REGIONAL OFFICE FOR Africa

http://www.afro.who.int/