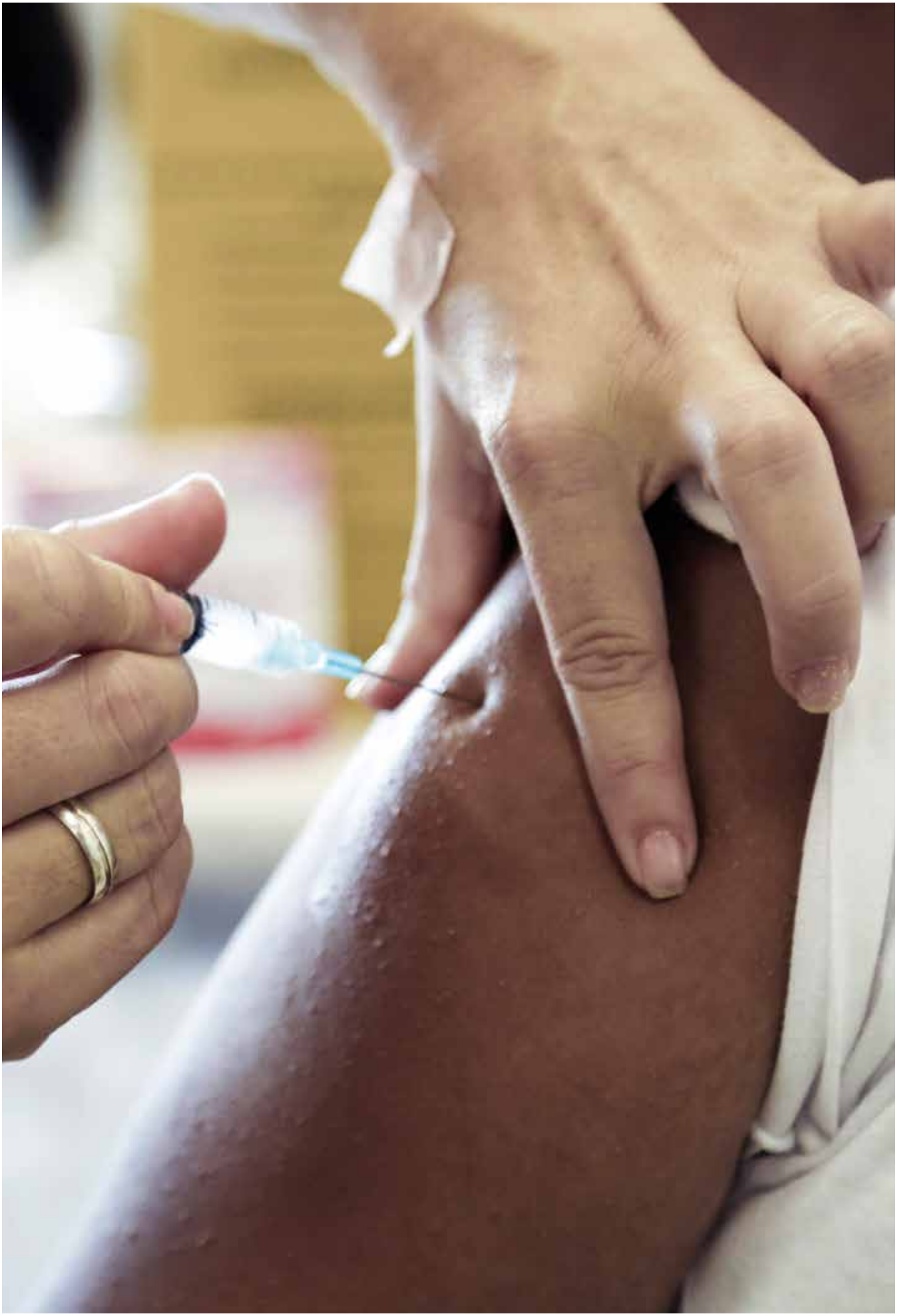
Mid-Level Management Course for EPI Managers

BLOCK III: Logistics

Module 8: Vaccine management

World Health Organization
REGIONAL OFFICE FOR Africa



Mid-Level Management Course for EPI Managers

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BLOCK III: Logistics

Module 8: Vaccine management

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Abbreviations and acronyms

AFP	acute flaccid paralysis
BCG	Bacillus Calmette-Guérin (vaccine against TB)
CCM	cold chain monitoring
CFC	chlorofluorocarbon
DANIDA	Danish International Development Agency
DoV	Decade of Vaccines
DT	diphtheria-tetanus (vaccine)
DTP	diphtheria-tetanus-pertussis-containing (vaccine)
EEFO	earlier expiry first out
EPI	Expanded Programme on Immunization
EVM	effective vaccine management
FCV	full course vaccination
FIC	fully immunized child
FIFO	first in first out
GAPPD	Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea
GIVS	Global Immunization Vision and Strategy
GSM	global system for mobile communication
GVAP	Global Vaccine Action Plan (2011–2020)
HepB	hepatitis B vaccine
Hib	*Haemophilus influenzae* type b (vaccine)
HPV	human papilloma virus
IMCI	Integrated Management of Childhood Illness
MDVP	multi-dose vial policy
MMR	measles, mumps, rubella
MOH	Ministry of Health
NID	national immunization day
OPV	oral polio vaccine
Penta	pentavalent (vaccine having five antigens)
PPP	public-private partnerships
RED/REC	Reaching Every District/Reaching Every Community
RSPI	Regional Strategic Plan for Immunization (2014–2020)

SIAs	supplementary immunization activities
SMT	stock management tool
TT	tetanus toxoid
UNICEF	United Nations Children's Fund
VAR	vaccine arrival report
VPD	vaccine-preventable disease
VVM	vaccine vial monitor
VWR	vaccine wastage rate
WHO	World Health Organization

Glossary

Auto-disable syringe	A specially modified disposable syringe with a fixed needle that is automatically disabled by plunger blocking after it has been used once.
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, syringes and safety boxes. It does not necessarily imply that things are tied together physically.
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. The 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.
Combination vaccine	A vaccine consisting of several components or antigens (e.g. DTP, DTP-HepB or DTP-HepB-Hib, etc.).
Diluents	A liquid used to reconstitute freeze-dried/lyophilized vaccine. Each such vaccine has its own diluents that cannot be used to reconstitute any other vaccine.
Expiry date	Date after which the vaccine, diluents and other consumables (e.g. syringes, needles) should not be used for the purpose of immunization due to possible loss of potency (vaccines) or durability (consumables and other items).
Indicator	A variable used to measure progress towards the achievement of targets and objectives. It is used to compare performance in terms of efficiency, effectiveness and results. It is also used to measure impact of interventions.
Inventory	A physical count and assessment of the state and functionality of the equipment and other materials used in the cold chain.
Logistics	A group of operations that include 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 ensure smooth running of the equipment and transport facilities related to the cold chain.
Reconstruction of vaccine	To restore to former condition of freeze-dried vaccines using specific diluents.
Supervision	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 etc. that help supervisors to assess the situation, and health workers to improve performance.

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 (8) titled *Vaccine management* is part of Block III: Logistics.

1.2 Purpose of the module

The aim of this module is to update EPI managers and immunization management teams with the concepts and techniques of vaccine management. The module will also help EPI managers to renew their immunization logistics support systems in order to address operational weaknesses.

1.3 Target audience

The module is intended for EPI managers at all levels of the national health system.

1.4 Learning objectives

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

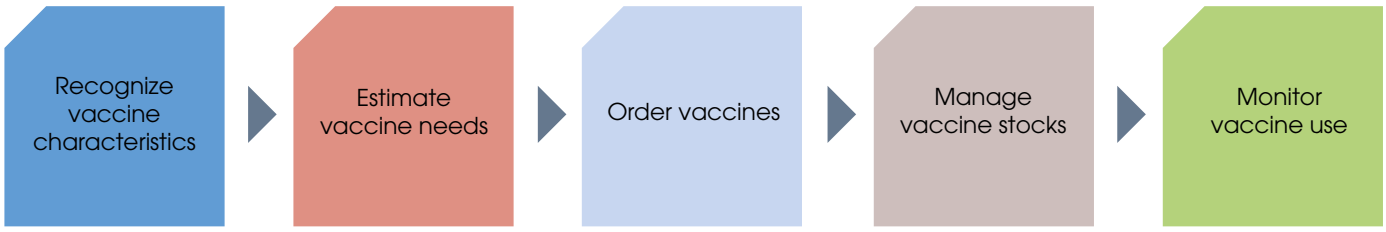
- Explain the methods used in forecasting vaccine needs:
  - explain parameters used for estimating vaccine needs
  - describe methods used for estimating vaccine needs.
- Apply the standards in ordering vaccines:
  - define supply parameters (supply interval, lead time)
  - determine stock levels (safety/reserve stock, maximum stock levels)
  - calculate total quantity of vaccines to be ordered.
- Manage vaccines stocks
  - determine vaccine acceptance criteria
  - categorize vaccines, diluents and supplies per storage conditions
  - demonstrate vaccine and diluents arrangements
  - explain the technique of shake test
  - explain vaccine and diluents distribution principles
  - design stock recording system.
- Apply the policies on monitoring vaccine use
  - interpret vaccines control indicators (vaccine vial monitor – VVM)
  - apply WHO policy on the use of opened multi-dose vials of vaccine in subsequent immunization sessions (multi-dose vial policy – MDVP)
  - categorize and calculate vaccines wastage.

1.5 Contents of the module

This module contains the sections shown below.

1.6 How to use this module

After discussing the concepts governing the management of vaccines and examining the various approaches suggested, each participant will be required to do the practical exercises. At the end of the exercises, participants will discuss the solutions with the facilitators or in plenary session.



2. Recognize vaccine characteristics

Vaccines are biological products prepared from killed or attenuated (weakened) virus or bacteria or their toxins, used for vaccinating people to induce specific immunity against an infectious disease. The vaccine products are available from different manufacturers with different characteristics targeting the same disease. The knowledge of those characteristics and their associated implications is important in order to optimally organize supply chain operations and to deliver safe vaccination services. Table 2.1 summarizes characteristics of most of the current vaccines being used in public health immunization programmes globally.

Table 2.1 Summary of different vaccines, their characteristics, presentation and recommended storage temperatures

Vaccine	Characteristics	Route of inoculation[3]	Formulation/ presentation	Handling procedures	Storage temperature
BCG	Live vaccine	ID	Lyophilized with diluents Multi-dose ampoules	Avoid exposure to sunlight Diluents should be refrigerated before mixing with vaccine Diluents should never be frozen	+2°C to +8°C
Diphtheria Pertussis Tetanus (DPT)	Inactivated vaccine toxoid	IM	Liquid Multi-dose vial	Never freeze	+2°C to +8°C
DPT-HepB-Hib (pentavalent vaccine or Penta)	Hib conjugated vaccine, HepB vaccine DPT (see above)	IM	Liquid Multi-dose/ single-dose vial	Never freeze	+2°C to +8°C
Hib	Conjugated vaccine	IM	Lyophilized or liquid Multi-dose/ single-dose vial	Diluents should be refrigerated before mixing with vaccine Hib liquid vaccine should never be frozen	+2°C to +8°C
HepB	Recombinant vaccine	IM	Liquid Multi-dose/ single-dose	Never freeze	+2°C to +8°C
Oral polio (OPV)[4]	Live attenuated virus vaccine	Oral	Liquid Multi-dose vial or plastic tube	Avoid exposure to light	+2°C to +8°C (or -20°C)
Inactivated polio vaccine (IPV)[5]	Inactivated vaccine	IM	Liquid Prefilled syringes/multi-dose vial	Never freeze	+2°C to +8°C

3 ID intradermal; IM intramuscular; SC subcutaneous.
4 OPV comes in trivalent formulation using Sabin Types 1, 2 and 3. Special formulations have been approved for use in polio eradication efforts; a bivalent formulation has been approved using Types 1 and 2.
5 Inactivated IPV vaccine is a trivalent formulation, Types 1, 2 and 3.

Vaccine	Characteristics	Route of inoculation[3]	Formulation/ presentation	Handling procedures	Storage temperature
Yellow fever	Live attenuated virus vaccine	SC	Lyophilized with diluents Multi-dose/ single-dose	Avoid exposure to sunlight Diluent should be refrigerated before mixing with vaccine but never be frozen	+2°C to +8°C (or -20°C)
Rotavirus	Live attenuated virus vaccine	Oral	Lyophilized with diluents or liquid Single-dose plastic tube or applicator	Avoid exposure to sunlight Prefilled syringe and lyophilized vaccine should be refrigerated but never be frozen	+2°C to +8°C
Measles	Live attenuated virus vaccine	SC	Lyophilized with diluents Multi-dose/ single-dose	Avoid exposure to sunlight Diluents should be refrigerated previous to mixing with vaccine but never be frozen	+2°C to +8°C (or -20°C)
Measles Mumps Rubella (MMR)	Live attenuated virus vaccine	SC	Lyophilized with diluents Multi-dose/ single-dose	Avoid exposure to sunlight Diluents should be refrigerated before mixing with vaccine but never be frozen	+2°C to +8°C (or -20°C)
Measles Rubella (MR)	Live attenuated virus vaccine	SC	Lyophilized with diluents Single-dose/ multi-dose	Avoid exposure to sunlight Diluents should be refrigerated prior to mixing with vaccine but never be frozen	+2°C to +8°C (or -20°C)
Pneumococcal	Conjugated vaccine	IM	Liquid Multi-dose/ single-dose Prefilled syringes	Never freeze	+2°C to +8°C
Hepatitis B	Live attenuated virus vaccine	IM	Liquid, single- or multi-dose	Never freeze	+2°C to +8°C
Meningococcal A	Conjugated vaccine and Polysaccharide	IM	Lyophilized with diluents Multi-dose vial	Diluents should be refrigerated before mixing with vaccine but never be frozen	+2°C to +8°C
Human rabies – Vero cell	Inactivated vaccine	IM	Lyophilized with diluents	Never freeze	+2°C to +8°C
Influenza[6]	Live attenuated virus vaccine	Intranasal	Prefilled syringes	Avoid thawing/freezing	+2°C to +8°C
Influenza[6]	Inactivated vaccine	IM	Multi-dose vial Prefilled syringes	Never freeze	+2°C to +8°C
Human papilloma virus	Recombinant Vaccine	IM	Liquid Single and multi-dose vial	Never freeze	+2°C to +8°C

The storage condition for each vaccine is determined by their composition and formulation. Each vaccine has its own correct storage conditions as specified by the manufacturer, the National Regulatory Authority or the World Health Organization (WHO).

3 ID intradermal; IM intramuscular; SC subcutaneous.
6 Seasonal influenza vaccine, both inactivated and live attenuated formulations contain a trivalent mix, which may change from year to year.

Staff that handle vaccines should be fully informed regarding the correct storage temperature for each vaccine in order to assure that they remain potent. Failure to properly assure the required storage temperature may lead to damaging the vaccine and result in not providing the expected immune response and may cause an adverse event.

Exercise 1

For all groups.
Working individually, identify vaccine characteristics and indicate in which form the antigen is presented in the following vaccines.

Vaccines	**Vaccine characteristics**	**Formulation/presentation**
Yellow fever		
Rotavirus		
Measles		
Pneumococcal		
Meningococcal		
BCG		
OPV		
IPV		
Hib		
TT		
Pertussis		
HepB		
HPV		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3. Estimate vaccine needs

A prerequisite for estimating vaccine needs is the availability of reliable data. These data are necessary to control future orders as well as handling and use of vaccines. It will also help to determine cold chain needs and evaluate needs in relation to the waste to be eliminated.

A comprehensive vaccine management system comprises three main activities:

- Estimating vaccine needs and injection accessories in line with the multi-year plan and micro-plans.
- Monitoring the management of vaccine stocks and organizing vaccine distribution.
- Monitoring and supervision of vaccine use and injection accessories on the ground.

Common problems

- Vaccine needs are normally estimated at the national level with support from UNICEF and the WHO country office, with little or no participation of the regional, district or peripheral levels.
- Often there are serious discrepancies between vaccine needs forecasts and the objectives of the EPI multi-year plans.
- Management of vaccines is generally inadequate; often no one is held responsible for loss of vaccines; and monitoring and control systems are weak.

Vital considerations and concerns

- Vaccine producers manufacture vaccines only when confirmed orders are placed.
- Vaccine producers have limited manufacturing capacity.
- Vaccines are becoming increasingly expensive, particularly new vaccines.

Advantages of an accurate forecasting vaccine needs

- Efficient control of immunization programmes by managers.
- Elimination of shortages or over-stocking of vaccines.
- Enhancing the capacity of districts to develop more accurate micro-plans.
- Increased efficiency of vaccine use, and reduction of wastage.
- Accurate estimation of financial resources when creating budget lines for purchasing vaccines.
- Assist in monitoring the progress of immunization in relation to the target coverage.

Three methods are commonly used to estimate vaccine needs based on:

- target population
- previous consumption
- size of immunization sessions.

3.1 Estimating vaccine needs on the basis of target population

To estimate vaccines needs based on the target population, a number of parameters for conducting immunization activities are necessary. They include:

- target population
- immunization schedule, i.e. number of doses per target
- immunization coverage targets
- wastage rate.

3.1.1 Target population

The target population is the number of recipients (children, men and/or women) within the targeted age groups for immunization. The target population in most immunization programmes consists of women (for maternal vaccinations), children (for infant vaccinations and second year of life vaccinations), adolescents (for school and HPV vaccinations) and other specific groups (for adults and risk group vaccinations).

Table 3.1 Example of EPI target population according to type of immunization activity

Target population	Routine	Campaign				School vaccination
		Polio	Measles	TT	MenAfriVac	
Children from 0–11 months						
Children from 0–23 months	X					
Children from 0–59 months		X				
Children from 9–59 months			X		X	
Children from 9 months–14 years			X		X	
Adolescent girls 9–15 years					X	X
Pregnant women	X				X	
Women of childbearing age	X			X	X	

The target population will be obtained by multiplying the total population by the percentage of the corresponding age bracket. However, these age groups are purely informative and may vary considerably from one country to the other depending on demographic pattern and the prevailing national immunization policy.

Table 3.2 Example of calculation of EPI target populations (total population – 20 000 000)

Target populations	% of total population	Number of people
Children from 0–11 months	4	800 000
Children from 0–59 months	20	4 000 000
Children from 9 months–14 years	45	9 000 000
Children 9–59 months	17	3 400 000
Adolescent girls	2	400 000
Pregnant women	5	1 000 000
Women of childbearing age	23	4 600 000
Meningitis A preventive SIAs	70	14 000 000

3.1.2 Immunization schedule

The immunization schedule determines the age limits and the number of doses required for the full immunization of each target child and women of childbearing age for each given antigen.

WHO provides countries with indicators on the number of vaccine doses per antigen that should be administered to each individual in the target population to ensure that the person is fully immunized. In this regard, WHO recommends the following standard immunization schedule (Table 3.3),[7] although individual countries may adapt it to their epidemiological, health and even financial situation.

7 http://www.who.int/immunization/documents/positionpapers/

Table 3.3 Summary of WHO position papers – recommendations for routine immunization ("Table 1")

(updated March 2017)

Table 2: Summary of WHO Position Papers - Recommended Routine Immunizations for Children

Antigen		Age of 1st Dose	Doses in Primary Series	Interval Between Doses			Booster Dose	Considerations (see footnotes for details)
				1st to 2nd	2nd to 3rd	3rd to 4th		
Recommendations for all children								
BCG [1]		As soon as possible after birth	1					Exceptions HIV
Hepatitis B [2]	**Option 1**	As soon as possible after birth (<24h)	3	4 weeks (min) with DTP1	4 weeks (min) with DTP3			Premature and low birth weight Co-administration and combination vaccine High risk groups
	Option 2	As soon as possible after birth (<24h)	4	4 weeks (min) with DTP1	4 weeks (min) with DTP2	4 weeks (min),with DTP3		
Polio [3]	**bOPV + IPV**	6 weeks (see footnote for birth dose)	4 (IPV dose to be given with bOPV dose from 14 weeks)	4 weeks (min) with DTP2	4 weeks (min) with DTP3			bOPV birth dose Transmission and importation risk criteria
	IPV / bOPV Sequential	8 weeks (IPV 1st)	1-2 IPV 2 bOPV	4-8 weeks	4-8 weeks	4-8 weeks		
	IPV	8 weeks	3	4-8 weeks	4-8 weeks		(see footnote)	IPV booster needed for early schedule (i.e. first dose given <8 weeks)
DTP-containing vaccine [4]		6 weeks (min)	3	4 weeks (min) - 8 weeks	4 weeks (min) - 8 weeks		3 Boosters 12-23 months (DTP-containing vaccine); 4-7 years (Td); and 9-15 yrs (Td)	Delayed/ interrupted schedule Combination vaccine; maternal immunization
***Haemophilus influenzae* type b** [5]	**Option 1**	6 weeks (min) 59 months (max)	3	4 weeks (min) with DTP2	4 weeks (min) with DTP3		(see footnote)	Single dose if >12 months of age Not recommended for children > 5 yrs Delayed/ interrupted schedule Co-administration and combination vaccine
	Option 2		2-3	8 weeks (min) if only 2 doses 4 weeks (min) if 3 doses	4 weeks (min) if 3 doses		At least 6 months (min) after last dose	
Pneumococcal (Conjugate) [6]	**Option 1**	6 weeks (min)	3	4 weeks (min)	4 weeks		(see footnote)	Vaccine options Initiate before 6 months of age Co-administration HIV+ and preterm neonates booster
	Option 2	6 weeks (min)	2	8 weeks (min)			9-15 months	
Rotavirus [7]	**Rotarix**	6 weeks (min) with DTP1	2	4 weeks (min) with DTP2				Vaccine options Not recommended if > 24 months old
	Rota Teq	6 weeks (min) with DTP1	3	4 weeks (min) - 10 weeks with DTP2	4 weeks (min) with DTP3			
Measles [8]		9 or 12 months (6 months min, see footnote)	2	4 weeks (min) (see footnote)				Combination vaccine; HIV early vaccination; Pregnancy
Rubella [9]		9 or 12 months with measles containing vaccine	1					Achieve and sustain 80% coverage Combination vaccine and Co-administration; Pregnancy
HPV [10]		As soon as possible from 9 years of age (females only)	2	6 months (min 5 months)				Target 9-14 year old girls; Multi-age cohort vaccination; Pregnancy Older age ≥ 15 years 3 doses HIV and immunocompromised

Refer to http://www.who.int/immunization/documents/positionpapers/ for table & position paper updates.

This table summarizes the WHO vaccination recommendations for children.The ages/intervals cited are for the development of country specific schedules and are not for health workers.

National schedules should be based on local epidemiologic, programmatic, resource & policy considerations. While vaccines are universally recommended, some children may have contraindications to particular vaccines.

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Table 2: Summary of WHO Position Papers - Recommended Routine Immunizations for Children (updated March 2017)

Antigen		Age of 1st Dose	Doses in Primary Series	Interval Between Doses			Booster Dose	Considerations (see footnotes for details)
				1st to 2nd	2nd to 3rd	3rd to 4th		
Recommendations for children residing in certain regions								
Japanese Encephalitis [11]	**Inactivated Vero cell-derived**	6 month	2 generally	4 weeks (generally)				Vaccine options and manufacturer's recommendations; Pregnancy; Immunocompromised
	Live attentuated	8 months	1					
	Live recombinant	9 months	1					
Yellow Fever [12]		9-12 months with measles containing vaccine	1					
Tick-Borne Encephalitis [13]		≥ 1 yr FSME-Immun and Encepur ≥ 3 yrs TBE_Moscow and EnceVir	3	1-3 months FSME-Immun and Encepur 1-7 months TBE-Moscow and EnceVir	5-12 months FSME-Immun and Encepur 12 months TBE-Moscow and EnceVir		At least 1 Every 3 years (see notes)	Definition of high-risk Vaccine options Timing of booster
Recommendations for children in some high-risk populations								
Typhoid [14]	**Vi PS**	2 years (min)	1				Every 3 years	Definition of high risk
	Ty21a	Capsules 5 years (min) (see footnote)	3 or 4 (see footnote)	1 day	1 day	1 day	Every 3-7 years	Definition of high risk
Cholera [15]	**Dukoral (WC-rBS)**	2 years (min)	3 (2-5 years) 2 (≥6 years)	≥ 7 days (min) < 6 weeks (max)	≥ 7 days (min) < 6 weeks (max)		Every 6 months Every 2 years	Minimum age Definition of high risk
	Shanchol and mORCVAX	1 year (min)	2	14 days			After 2 years	
Meningococcal [16]	**MenA conjugate**	9-18 months (5µg)	1					Definition of high risk; Vaccine options; 2 doses if < 9 months with 8 week interval
	MenC conjugate	2-11 months	2	8 weeks			After 1 year	Definition of high risk; Vaccine options
		≥12 months	1					
	Quadrivalent conjugate	9-23 months	2	12 weeks				Definition of high risk; Vaccine options
		≥2 years	1					
Hepatitis A [17]		1 year	At least 1					Level of endemicity; Vaccine options; Definition of high risk groups
Rabies [18]		As required	3	7 days	14-21 days		(see footnote)	Definition of high risk, booster
Dengue (CYD-TDV) [19]		9 years (min)	3	6 months	6 months			Seroprevalence
Recommendations for children receiving vaccinations from immunization programmes with certain characteristics								
Mumps [20]		12-18 months with measles containing vaccine	2	1 month (min) to school entry				Coverage criteria > 80%; Combo vaccine
Seasonal influenza (inactivated tri- and qudri-valent) [21]		6 months (min)	2 (<9 years) 1 (≥ 9 years)	4 weeks			Revaccinate annually: 1 dose only (see footnotes)	Priority risk groups, especially pregnant women Lower dosage for children 6-35 months
Varicella[22]		12-18 months	1-2	4 weeks to 3 months per manufacturer recommendations				Achieve & sustain ≥ 80% coverage Pregnancy Co-admin with other live vaccines

3.1.3 Immunization coverage objectives

The objective in terms of annual coverage for each antigen is generally dictated by the national immunization action plan, or the micro-plan at district level. These plans determine the percentage of each group of the target populations to be vaccinated. Table 3.4 gives an example of immunization coverage by antigen and applied strategy.

Table 3.4 Example calculation of the population to be vaccinated according to the coverage objectives, based on total population of 20 000 000

Vaccine	Age group	Target population	Vaccination coverage (%)	Vaccination strategy	Number of children and women to be vaccinated
BCG	0–11 months	740 000	90	Routine	666 000
Polio	0–11 months	800 000	90	Routine	720 000
DTP-HepB-Hib	0–11 months	800 000	80	Routine	640 000
Measles	0–11 months	800 000	80	Routine	640 000
PCV	0–11 months	800 000	80	Routine	640 000
Rota	0–11 months	800 000	80	Routine	640 000
TT	Pregnant women	800 000	25	Routine	200 000
TT	Childbearing age women	4 600 000	75	Campaigns	3 450 000
Polio	0–59 months	4 000 000	100	NIDs	4 000 000
Measles	9–59 months	3 400 000	100	Campaigns	3 400 000
Measles	9 months–14 years	9 000 000	100	Campaigns	9 000 000

Note: the above calculation should also take into consideration the annual population growth rate to determine the target population for each planning year.

3.1.4 Vaccine wastage rate and wastage factor

During immunization, the number of vaccine doses consumed is generally higher than the number of individuals vaccinated. The number of doses in excess represents "lost doses" or vaccine wastage. There are two types[8] of vaccine wastage in immunization programmes:

- The remaining doses of vials opened thrown away after the immunization session, in line with the WHO multi-dose vial policy (MDVP).
- Unopened/closed vials discarded during storage, handling, and transportation of the vaccines due to temperature damage or expiry.

These two types of vaccine wastage should be taken into account in the estimation of vaccine needs. The opened vial wastage will depend on both the characteristics of the vaccine used (vial size, status of MDVP) and the context of service delivery (session size and frequency). This should be established based on experience. Although modelling[9] can help to determine the anticipated opened vial wastage for each immunization programme. The unopened/closed vial wastage should account for a maximum of 1% per supply chain level, as per the effective vaccine management (EVM) indication.

Currently, the use of the wastage rate for estimating vaccine needs is rather a matter of what each and every immunization programme experiences. Vaccine wastage should be monitored at all levels and data used for forecasting future needs. However, when there is uncertainty in the monitoring of vaccine wastages, for the purpose of estimating vaccine needs, some guiding figures could be used (see Table 3.5).

8 WHO (2003). WHO/V&B/03.18. Monitoring of vaccine wastage, Guidelines for programme managers.
9 WHO/EPI is developing a modelling for estimating opened vial wastage that countries can use when available.

Table 3.5 WHO indicative wastage rates used for planning purposes

Vaccine presentations	Wastage rate	
	Routine	Campaigns
Single dose	5%	5%
2 or 5 dose, regardless the status of MDVP	10%	10%
10 or 20 dose – if opened vial can be reused in subsequent sessions	20%	15%
10 or 20 dose – if opened vial must be discarded at end of session	40%	15%
20 dose or more – if opened vial must be discarded at end of session	50%	20%

Knowing the wastage rate helps to determine the wastage factor, which is one of the parameters used to estimate vaccine needs.

The formula to calculate the wastage factor on the basis of wastage rates:

$$\text{Wastage factor} = \frac{100}{(100 - \text{wastage rate})}$$

Where: "100" is the total number (100%) of vaccine doses supplied and "wastage rate" is the number of doses (in %) waste

Example:

Wastage rate = 30%

$$\text{Wastage factor} = \frac{100}{(100 - 30)} \quad \frac{100}{70} = 1.43$$

Exercise 2

Complete the table by calculating the wastage factor corresponding to the wastage rates given.

Wastage rates (%)	5	10	15	20	25	30	35	40	45	50	55	60	65	70
Wastage factors														

At the end of your calculations, check your answers with the facilitator.

Once the parameters have been determined, it is possible to calculate vaccine needs based on the target population.

Formula for calculating vaccine needs based on target population:

Parameters for calculating vaccine needs (doses)	Code
Target population	Pt
Number of doses in the schedule	Dn
Vaccination coverage targeted	Ct
Wastage factor	Wf
Annual needs in vaccines = Pt x Dn x Ct x Wf	

Example: Calculation of annual needs of DTP-HepB-Hib vaccines for a given target population

Pt		Dn		Ct		Wf		Needs
Children from 0–11 months	x	Penta doses of the immunization schedule	x	Vaccination coverage (%)	x	Children from 0–11 months	=	Total doses/year
10 000		**3**		**90% (0.9)**		**1.05 (Wf 5%)**		**28 350**

Note: For SIAs only this method is used.
Remarks: The manager must be aware that overestimation of vaccine quantities can lead to over stocking and hence high wastage. However, underestimation can lead to shortage of vaccine. When using this method, managers should use the most accurate population estimate, realistic coverage and validated wastage rate.

3.2 Estimating vaccine needs on the basis of previous consumption

The method of estimating vaccines needs based on previous vaccines consumption consists of calculating retrospectively the quantity of vaccines consumed during the previous period. The resulting quantity is thereafter adjusted if necessary (for instance when there is a growth in the population) for the current or any future period. This method is based on a relatively stable demand supported by reliable stocks management data.

The data required for estimating vaccines needs based on previous consumption are:

- stock available at the beginning of a given period;
- vaccines received during the same period;
- stock at the end of the given period; and
- number of unopened vaccines vials lost (destroyed, frozen or affected by high temperatures or expired during the same period).

Formula for calculating vaccine needs based on the previous consumption:

Parameters for calculating vaccine needs (doses)	Code
Initial stock at the beginning of the period	I
Vaccines received during the period	R
Stock remaining at the end of the period	F
Lost, destroyed or expired doses	L
Vaccines needs = (I+R) - (F+L)	

Example: Calculation of annual needs of DTP-HepB-Hib on the basis of previous consumption

I		R		F		L		Needs
Initial stock at the beginning of the year	+	Quantity received during the year	-	Stock at the end of the year	-	Quantity lost during the year	=	Total annual doses needed
10 000		**50 000**		**20 000**		**5 000**		**35 000**

This method may be difficult to apply for periods exceeding one year, but it is useful when making short-term orders. The method cannot take into consideration changes that may occur during the course of the planning period (e.g. seasonal migrations, change of the number of target population during immunization campaigns, etc.).

3.3 Estimating vaccine needs on the basis of the size of vaccination sessions

The data required for estimating needs based on the size of vaccination sessions are:

- number of vaccination posts/sites in the catchment area;
- number of optimal sessions per post/site for defined period;
- estimated target population per post/site for the same period; and
- formula for monthly needs.

For vaccines which can be used for subsequent sessions:
{(Target population/number sessions) / vial size} x number doses schedule = number vials

For vaccines which should be discarded at end of session
{(Target population x number doses schedule) / number sessions)/vial size} x number sessions = number vials

Number of weeks of operation in the year

- number of vaccination sessions per week
- number of vials opened per session (average)
- number of doses per vial.

To estimate the frequency and adequacy of vaccination sessions, the following data could be used:

- number of organized vaccination sessions
- number of children vaccinated per session.

Formula for calculating vaccines needs based on the size of past vaccination sessions:

Parameters for calculating vaccine needs (doses)	Code
Number of vaccination posts	Posts
Number of weeks of operation in the year	Weeks
Number of vaccination sessions per week	Sessions
Number of vials opened per vaccination session	Vials
Number of doses per vial	Doses
Vaccines needs = posts x weeks x sessions x vials x doses	

Example: Calculation of annual needs of DTP-HepB-Hib according to past vaccination sessions

Number of vaccination posts	x	Number of weeks in operation	x	Number of sessions per week	x	Number of vials per session	x	Number of doses per vial	=	Total annual doses needed
20		48		3		2		10		57 600

This method may be appropriate for programmes that cannot determine their vaccine wastage rates or control their vaccine stock management. But it helps to control the size of the sessions, thereby limiting the number of vials opened per vaccination session.

3.4 Comparative advantages of the three methods of estimating vaccine needs

If target population data are available (accurate or not), the preferred option at national, regional, district and service delivery levels is the target population method. If target population data are not available, the preferred option is the "consumption" method – if there is good inventory management system without significant stock-outs. The third option is the "session" method. At service delivery level, the target population method should be applied for annual forecasting while the "session" method would be more appropriate to calculate monthly needs. Table 3.6 summarizes the comparative advantages of the three methods for estimating vaccine needs.

Table 3.6 Comparative advantages of vaccine needs forecasting methods

Method based on:	Advantages	Constraints	Comments	Preferred application
Target population	Facilities active and accurate planning Assists in monitoring vaccine wastage	Unreliable demographic data	Can be used for both short- or long-term planning	Central and intermediate levels Supplementary immunization activities (SIA)
Previous consumption	Adequate for short periods Does not depend on target population data	Difficult to apply for long periods Planning is passive. In some cases the previous high or low consumption may be occasional thus misleading when the next year needs are calculated	Can be used for both short- or long-term planning	Countries with a stable EPI and good vaccine stock management system Convenient to use at subnational and health facility levels with high coverage
Vaccination session	Makes it easy to control the size of immunization sessions	Reduces health workers' interest in the results Promotes passive planning Monitoring of vaccine wastage rates is not involved	Not convenient for national level	At the fixed health facility level (fixed posts) Outreach posts

Note: Remember that vaccine orders are placed at time intervals that need to be determined by the programme manager when developing the distribution plan.

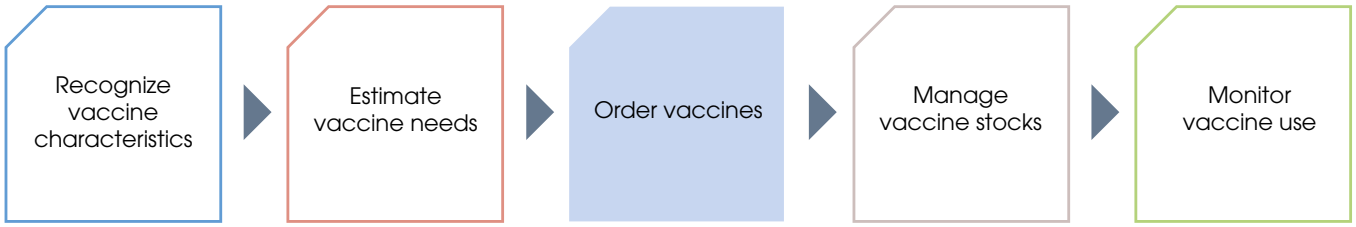
Exercise 3

For all groups.

Task 1: Using the data below, estimate the vaccine needs using the target population method discussed above. The total population is 725 000 inhabitants.

Task 2: Discuss the challenges of the three methods you may have in your country/within your group.

Vaccine	Target population (%)	Number of doses in calendar	Coverage targeted	Wastage rate	Vaccine needs
BCG	4%	1	90%	60%	
OPV	3.8%	4	90%	20%	
IPV	3.8%	1	90%	40%	
Penta	3.8%	3	90%	10%	
Measles/MR	3.8%	2	90%	30%	
PCV	3.8%	3	90%	5%	
Rota	3.8%	2	90%	5%	
TT/Td	4%	2	80%	20%	



4. Order vaccines

Every order for vaccines should take into account the following considerations:

- Avoid stock shortages.
- Avoid situations where vaccines expire during their storage period due to stock excess.
- Ensure that there are adequate cold chain storage facilities (with adequate capacity and at appropriate temperature).
- Ensure that vaccines ordered are in conformity with standards recommended by the national regulatory authority, or by WHO and UNICEF.
- Ensure that stocks of consumables (e.g. diluents, syringes and safety boxes) are available and sufficient.
- Ensure that the WHO and UNICEF's "bundling" strategy is adopted.

Since all the annual quantities of vaccine cannot be used or stored at once, portions of the total annual need are supplied periodically to each storage/service point. A formal requisition/dispatch process should be put in place and followed to implement these deliveries. Stock levels will also be determined and used as triggers for placing orders.

Remember: Long storage periods risk expiration of vaccines!

4.1 Defining vaccine supply period

Placing the orders and subsequent deliveries should be programmed and implemented in the most efficient way to meet demand. This implies defining periods of vaccine supply, which will depend on:

- supply chain level (national, subnational, service delivery)
- quality of the cold chain
- availability of cold storage capacity
- performance of stock management system, including vaccine monitoring and distribution.

If the cold chain is not reliable or does not have enough capacity, the supply period should be adjusted to minimize the quantity of the stock.

For example, a health post will have a shorter period of vaccines supply (one to two weeks) than a district store (one month), where the cold chain is more reliable. Similarly, a regional vaccine store will have shorter period of supply than the central stores, because the regional store is more likely to experience power cuts or generator breakdowns.

Table 4.1 Generally recommended standard periods for vaccines supply

Location of the store	Supply period
Central store	Six months
Regional/provincial store	Three months
District store	One to three months
Health centre	One to two months

Avoid hoarding vaccines and storing them for too long. Depending on the geographic accessibility and season of the year, the above periods could be revised to suit local conditions.

4.2 Calculating quantities of vaccine for a supply period

The needs for a specific supply period or interval can be calculated using the following formula:

Formula: Q_{period}	=	$(Q_{year}/12) \times P_{supply}$
Where:		
Q_{period}	=	Vaccines needs for the period
Q_{year}	=	Annual vaccines needs
P_{supply}	=	Supply period or interval (in months)
12 represents the number of months in the year		

Note: The period/interval may be expressed in weeks, in this case 52 will be used, as the number of weeks in the year.

Example:

Number of doses required for 52 weeks (for a year)		=	10 000
Number of doses required for one week	10 000/52	=	193
Number of doses required for 12 weeks	193 x 12	=	2308

Sequence of calculation:

Number of doses required per year (52 weeks)	:	Number of weeks per year	x	Established supply period (12 weeks)	=	Number of doses for the desired supply period
10 000		**52**		**12**		**2316**

4.3 Defining safety stock level

The "safety" stock, also called "reserve" or "buffer" stock, is a provision made to cover unforeseen fluctuations of demand and unexpected delays in the delivery schedule. It can be established as a certain percentage of the supply period needs. It cannot be more than the supply period needs. The percentage is an indication of uncertainties with the supply at each supply chain level in each country. The more uncertainties, the higher the percentage should be set.

However, the safety stock should not be too low in order to avoid stock-out when there is unforeseen delay in delivery and/or unexpected increase in demand on one hand, and on the other hand it should not be too high to avoid over stocking. It is also referred to in this module as "minimum stock".

The safety or minimum stock can be established using the following formula:

Formula: $S_{reserve} = Q_{period}$ **x Reserve%** (to be determined for each facility)*

* In previous modules, 25% was used for reserve stock but this amount should not be considered as standard applicable for all! In this case, the reserve stock was taken as a quarter of the quantity of supply period.

Note:
The safety or minimum stock is not supposed to be consumed under normal circumstances. However, it should not be managed as a separate physical stock put aside in the store. It is a virtual amount and the entire physical stock should be managed and distributed according recommended principles, i.e. earlier expiry first out (EEFO), VVM status, first in first out (FIFO).

Example:

Number of doses required for a given supply period		=	10 000
Percentage desired as reserve stock		=	50%
Reserve or minimum stock (doses)	10 000 x 0.50	=	5000

Sequence of calculation:

Number of doses required for a given supply period	x	Percentage desired as reserve stock	=	Number of doses of reserve stock (doses)
10 000		**50%**		**5000**

4.4 Calculating maximum stock level

The "maximum" stock is the maximum number of vaccine doses that should be found in the store after a supply delivery. The maximum stock is the sum of the supply period needs plus the safety stock.

The maximum stock will help to determine the storage capacity needed.

The maximum stock can be calculated using the following formula:

Formula: $S_{maxi} = Q_{period} + S_{reserve}$

Example:

Quantity of doses required for a given supply period		=	10 000
Reserve stock (doses)		=	5000
Maximum stock (doses)	10 000 + 5000	=	15 000

Sequence of calculation:

Quantity of doses required for a given supply period	x	Quantity of doses of reserve stock	=	Quantity of doses of the maximum stock
10 000		**5000**		**15 000**

4.5 Calculating reorder stock level (or warning level)

The reorder stock or warning level is determined by the quantity of vaccine doses in stock at the time when it is **absolutely necessary** to place a new order. The reorder stock level takes into account the amount of vaccine that will be consumed between the placement of the order and the receipt/arrival of the new consignment, called the lead time. The lead time is therefore the time interval between the day the vaccines are ordered and the day they are delivered and received at the store.

This precaution is necessary to prevent the vaccine stock from dropping below the reserve (minimum) level before the new arrival. Ideally, a new consignment should arrive in the store just when the stock reaches the reserve or minimum stock level.

The lead time includes, the following:

- time for administrative processing the request
- time for preparing the consignment, including packaging, labelling
- time for shipment, including transport, transit, clearance and storing.

At the central level, the lead time may be up to three months and more. Within the same country, except for areas with really difficult access, the period from ordering and receiving vaccines at different levels of the supply chain (central to provincial, provincial to district or district to service points) should not exceed one to two weeks.

The reorder stock or warning level can be established using the following formula:

Formula: $S_{reorder} = S_{reserve} + (Q_{period} \times Lead_{time} / P_{supply})$

Where:

Leadtime = Time interval between the placement of order and the receipt of the consignment

The term **Qperiod x Leadtime /Psupply** represents the amount of vaccines consumed between the time when the vaccines are ordered and the time when they are received.

Note: The supply period and lead time should be expressed in the same units (months or weeks).

Example:

Quantity of doses required for a supply interval of 12 weeks		=	10 000
Lead time (in weeks)		=	2
Reserve stock (in doses)		=	5000
Reorder level (in doses)	10 000 x 2/12 +5000	=	6667

Sequence of calculation:

Doses required for a supply interval	x	Lead time over supply interval	+	Reserve stock	=	Reorder stock
10 000		**2/12**		**5000**		**6667**

Note: This formula is applicable to the central level where large quantities of vaccines are stored, and where the lead time is generally longer. For regional and district stores, where the quantities of vaccines are relatively smaller, and the lead times relatively shorter, one may consider the reserve stock equals to the reorder level.

4.6 Calculating total quantities of vaccine to be ordered

Once the above critical stock levels are established, the vaccine quantities to be ordered are calculated taking into account the stock balance in store at the time of placing the order, the maximum stock and the lead time.

The supply of vaccine may be based either on the reorder or warning stock level, or on a fixed delivery schedule, including, half-yearly, quarterly and monthly. Experience has shown that it is difficult to uphold the periodicity of vaccines supply since the consumption levels vary during the course of the year. A stock shortage may occur before the end of the period.

It is therefore recommended that an order be placed as soon as the stock of one vaccine reaches the reorder level. In this case, the order should cover all vaccines, including those that have not reached the reorder level.

The number of vaccine doses to be ordered can be calculated using the following formula:

General formula: $Q_{order} = S_{maxi} - S_{available} + (Q_{period} \times Lead_{time} / P_{supply})$

Example:

Needed doses for the supply period		=	10 000
Maximum stock (in doses)		=	15 000
Reorder stock		=	6667
Available stock (in doses)		=	4000
Supply period (in weeks)		=	12
Lead time (in weeks)		=	2
Quantity to be ordered (in doses)	15 000 - 4000 + (10 000 x 2/12)	=	12 667

Sequence of calculation:

Maximum stock	-	Stock available	+	Doses required for the lead time	=	Quantity to be ordered
15 000		**4000**		**10 000 x (2/12) = 1667**		**12 667**

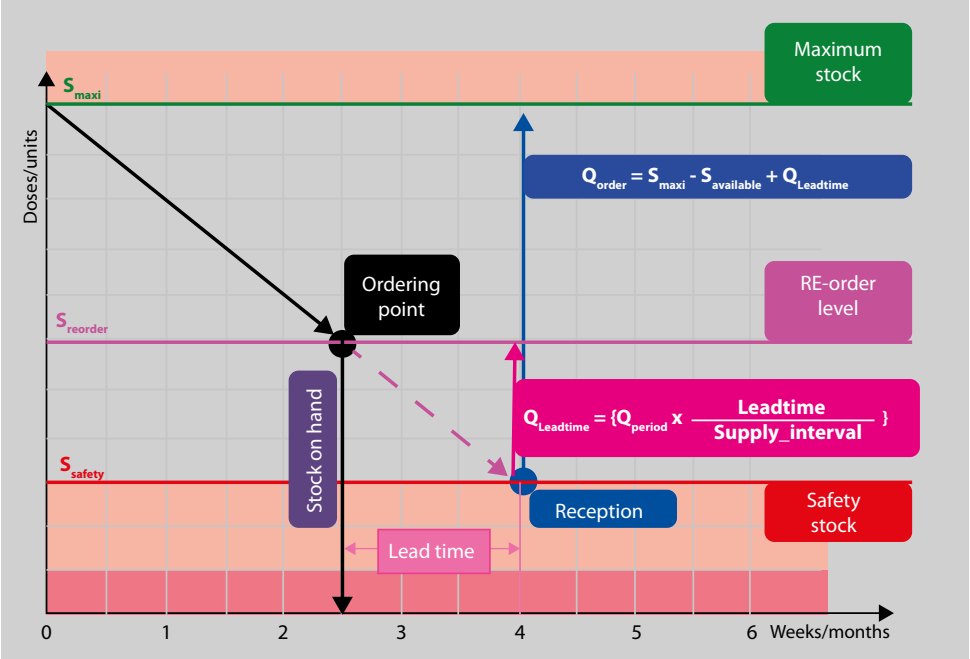
Note: Within the same country, except under special accessibility conditions, it takes only a few days from requisition to delivery of vaccines between the different administrative levels (central stores to provincial stores or, provincial stores to district stores). Hence, the term **(Qperiod x Leadtime/ Psupply)** becomes quite negligible, which explains why it is not taken into account in the formula used to order vaccines at these different levels. In this case, a short formula is used:

Short formula: $Q_{order} = S_{maxi} - S_{available}$

Once the number of vaccine doses to be ordered is determined, it is necessary to convert these doses into numbers of vials. The same vaccine may be available in different vial sizes (2, 5, 6, 10, 20, 50 doses etc.). The decision to order such and such vial size for a particular vaccine will have a direct impact on the cost, the vaccination strategies, wastage rate and the required storage capacity in the cold chain.

Figure 4.1 illustrates time to order level, which is determined on the basis of the maximum and minimum stock levels and according to the trend of vaccine consumption in weeks.

Figure 4.1 Graph of the vaccine order parameters



Exercise 2

Complete the table by calculating the wastage factor corresponding to the wastage rates given.

Vaccines	Target population	Number of doses	Target coverage	Wastage factors	Stock at hand	Minimum stock	Duration of storage	Number of doses/ vials
BCG	2700	1	95	2	To be det.	50%	3 months	20
OPV	2 700	4	90	1.33	To be det.	50%	3 months	20
Penta	2 700	3	90	1.05	To be det.	50%	3 months	1
Measles	2 700	1	80	1.43	To be det.	50%	3 months	10

Considering that the stocks available are taken into account at the time of placing the order, calculate the vaccine needs as follows:

a) quantity that you intend to use within three months
b) minimum stock
c) maximum stock
d) reorder level
e) quantity to be ordered
f) number of vials to be ordered per antigen.

To encourage participation in your group in this exercise and for saving time, form small subgroups within the group and assign each vaccine line to a subgroup for calculations. At the end of your work, show facilitator your results.

Refer to Annex 2 which provides summary calculations in vaccine management discussed above.

5. Manage vaccines stocks

The control of vaccines stocks is one of the main tasks of vaccine management. It consists of receiving and accepting vaccines, ensuring the required storing conditions and controlling the distribution of vaccines through the different structures (intermediary stores and immunization units) in order to ensure the quality of vaccines for immunization programmes.

5.1 Receiving delivered vaccines and supplies

A vaccine arrival report (VAR) is attached to each UNICEF vaccine international shipment. It is the responsibility of the programme manager, with support from UNICEF or WHO officers to ensure that all sections of the VAR are completed and returned to the UNICEF country office within the prescribed time. During transport and transit, the integrity of vaccines must be ensured through a reliable cold chain. Recipient agencies and governments should only accept vaccines if shipment procedures and quality assurance during the shipment have been guaranteed and followed. It is the responsibility of the programme manager to clear shipments through customs authorities upon arrival and prompt transfer to central vaccine stores. The VAR is a register for recording possible anomalies in vaccine shipment and the conditions of vaccines upon delivery. It is a basic and important document for claims in cases of litigation. A model of VAR and guidelines for completing it can be found in Annex 1. On arrival of vaccines or supplies, only qualified personnel should accept the delivery by following the steps below:

- Verify that all necessary documents are present and properly filled in.
- Check if the delivery address is correct.
- Check the status of the packaging (to see if the parcels have been opened and/or damaged).
- Check if the packaging conditions are met.
- Check the expiry dates of vaccines/supplies in all boxes.
- Check if the content is the same as written on the delivery slip and other accompanying documents.
- Check if the diluent is correct and its quantity corresponds to the vaccine.
- Check the status of shipping indicators/ temperature monitors for vaccine in **all boxes.**
- All the noted inconsistencies must be brought to the attention of the supervisor and the supplier for replacement if necessary.

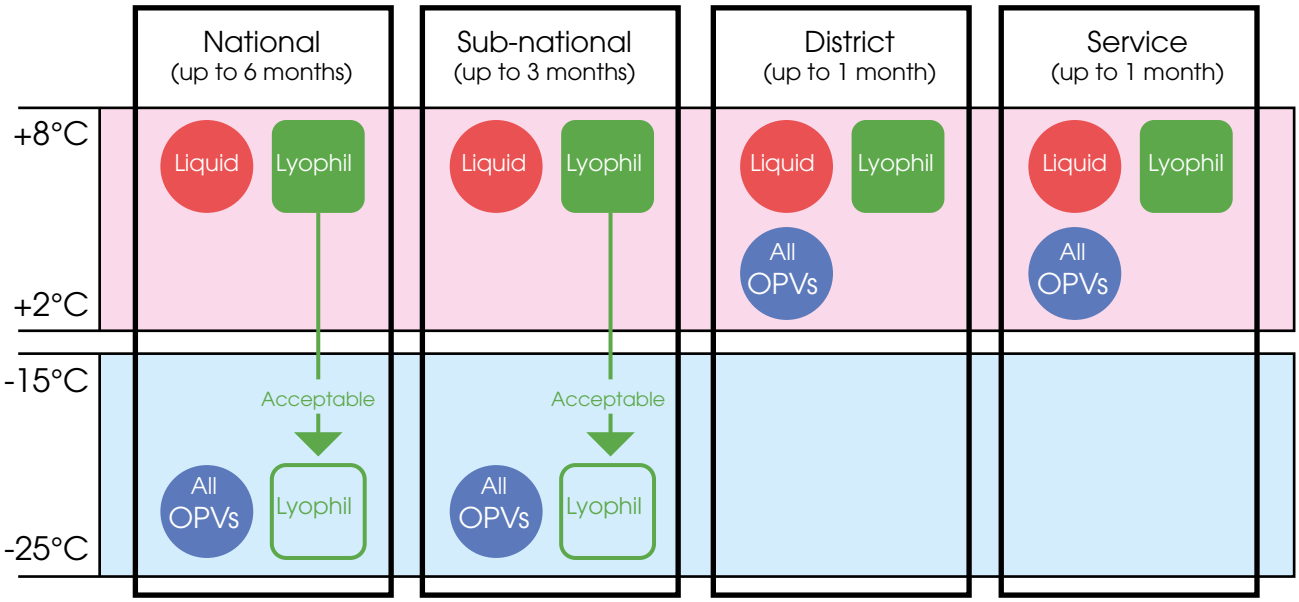
5.2 Storage, transport and handling of vaccines

Vaccines are delicate biological substances that *lose their potency when they are exposed to incorrect temperatures.* Once a vaccine has lost its potency through exposure to heat, for example, it is not possible to restore it even if the vaccine is later kept in normal temperatures.

Note: Countries who do not procure vaccines through UNICEF should adapt the VAR.

Figure 5.1 illustrates the time limit of vaccine storage and the required storage temperatures.

Figure 5.1 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.

5.2.1 Vaccine control indicators

Vaccines should be stored and transported at controlled temperatures. Temperature monitoring devices have been developed to indicate if vaccines have been stored and transported under the appropriate conditions. Temperature monitoring devices are tools for providing information on the vaccine storage temperature inside cold chain equipment. Users can determine the action to be taken based on the temperatures and other information provided by these devices. The following are examples are given for illustration.

If the temperature monitors show alarm for freezing:

- conduct "shake test"
- report the incident
- take actions to solve the problem (refer to Module 1: *A problem-solving approach to immunization services management*).

If the temperature monitor shows alarm for heat exposure: the VVM will indicate if the vaccine should be discarded or not. If the VVM status is at discard point or beyond the vaccine should not be removed from the cold chain and marked **DO NOT USE.**

- record the quantity in the stock register/card
- report the incident to upper level
- take/implement actions to solve the problem.

If there is no VVM:

- report to upper level of the situation
- keep the vaccines in the cold chain and not use until instructions are given
- take/implement action to solve the problem.

Vaccine to be discarded should be clearly marked **DO NOT USE** and removed from the cold chain.

5.2.2 End-to-end temperature monitoring

In order to maintain vaccine quality, it is essential to monitor the temperature of vaccines throughout the supply chain.

- Transportation of vaccine from the vaccines producer/supplier to the national (central) store in the country.
- Storage of the vaccine at the national (central) store.
- Transportation of vaccine along each step in the cold chain (subnational, regional, provincial, district stores) until and including the lowest distribution level.
- Storage of vaccine at each step of the cold chain (subnational, regional, provincial, district stores) until and including the lowest distribution level.
- Transportation of the vaccine from the lowest distribution level to the service delivery point (health centre or health post).
- Storage at the service delivery point (health centre or health post).
- Storage in passive containers (vaccine carriers or cold boxes) during transportation for outreach vaccination sessions.
- Storage in passive containers (vaccine carriers or cold boxes) during outreach vaccination sessions.

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 -25°C to -15°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.

Different temperature monitoring devices are available from different manufacturers. WHO recommends temperature monitoring devices based on the specific cold chain equipment application and the intended monitoring purpose. They can be categorized into three: condition indicators, temperature readers and temperature recorders.

Figure 5.2 Categories of vaccine temperature monitoring devices

Table 5.1 presents minimum requirements for temperature monitoring devices to be used for different cold chain equipment at different levels of the supply chain.

Table 5.1 Temperature measuring devices recommended for the cold chain

Cold chain equipment	Temperature monitoring devices	
	Recommended devices	**Minimum requirement**
Freezer rooms and vaccine freezers in primary or subnational stores	☐ Electronic continuous temperature monitoring and permanent record system, wired or wireless PLUS ☐ Temperature excursion alarm system with external communications facility (GSM or other) PLUS ☐ Permanent on site or remote data storage arrangement	☐ External digital thermometer or gas/vapour pressure dial thermometer ☐ Audio temperature alarm system ☐ Stem thermometer as back up device only
Cold rooms and vaccine refrigerators in primary or subnational stores	☐ Electronic continuous temperature monitoring and permanent record system, wired or wireless PLUS ☐ Temperature alarm system with external communications facility (GSM or other) PLUS ☐ Permanent on site or remote data storage arrangement ☐ Electronic freeze indicators	☐ External digital thermometer or gas/vapour pressure dial thermometer ☐ Electronic freeze indicator(s) ☐ Temperature alarm system ☐ stem thermometer ☐ 30-day electronic refrigerator temperature logger
Vaccine freezers in small subnational stores	☐ Alcohol stem thermometer	☐ Alcohol stem thermometer
Vaccine refrigerators in small subnational stores and health facilities	☐ 0-day electronic refrigerator temperature logger with integrated visual or external communications alarm ☐ Electronic freeze indicators	☐ Alcohol stem thermometer ☐ Electronic freeze indicator

Annex 3 provides a description of selected commonly used temperature monitoring devices.

Table 5.2 lists temperature fluctuations in cold chain equipment and provides suggested actions to resolve temperature irregularities.

Table 5.2a Cold rooms, vaccine refrigerators, refrigerated trucks, cold boxes, vaccine carriers

Temperature fluctuations	Suggested actions
Temperature between +2°C and +8°C	• **Situation is normal**, no action necessary
Temperature at or below 0°C	• **Vaccine at risk:** Take immediate action to correct the low temperature and ensure that the problem does not arise again • Inspect the freeze-sensitive vaccines and/or carry out a shake test to establish if any of the vaccines has been frozen • Frozen vaccine has to be tested in order to establish whether it is still potent or destroyed. Report should be made to your supervisor
Temperature between +8°C and +10°C	• If there has been a temporary power failure, **no further action is necessary** • Check that the refrigeration unit is working, monitor the situatin closely and take appropriate action if the temperature is not within the normal range at the time of the next inspection
Temperature above +10°C	• **Vaccine at risk:** Sample a few batches and check the VVM status • Take immediate action to implement the agreed contingency plan (taking into account that the PQS fridge test protocol does allow temperature excursions to 20°C for up to 20% of time in any five-day consecutive period), and make a report

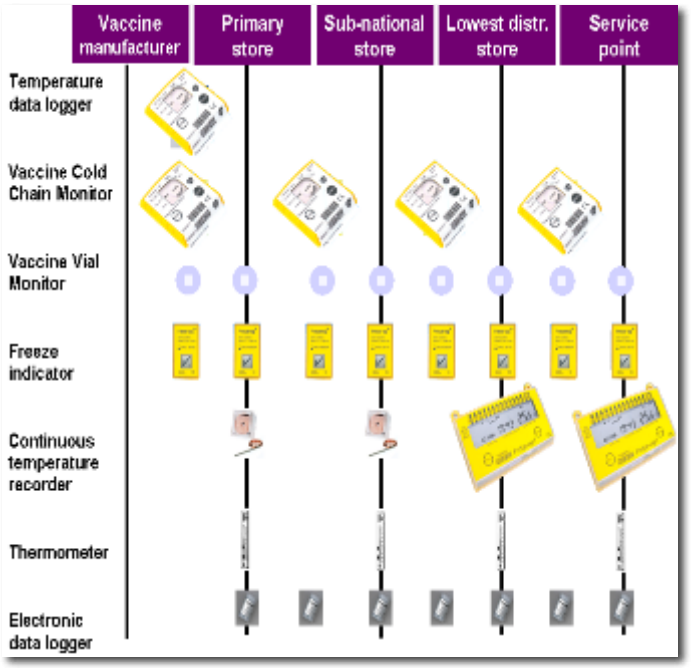
Table 5.2b Freezer rooms and freezers

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

Figures 5.3 Devices for temperature monitoring by level

Regardless the type of temperature monitoring device used, the following should be kept in mind:

- Selection of the device should be based on the application and the capacity to manage and analyse the data provided by the device.
- The device is calibrated correctly and is providing reliable data.
- Temperature devices for use in the cold chain should be standardized to reduce management and inventory costs.
- Users will require training when any new device is introduced.
- Supervisors should routinely review the temperature data recorded at different levels of the cold chain to identify problems and take action to correct them.



Exercise 5

For all groups. All three parts should be conducted during the same session.

Task 1: A country monitors the temperature of its cold chain from end to end. It plans, however, to introduce a new vaccine that will require additional cold chain capacity. Additional cold chain equipment is required at all levels of the cold chain to accommodate the new vaccine. Will any new temperature monitoring equipment be required? If so, what equipment would be appropriate to ensure "end-to-end" monitoring and where should this equipment be installed or used?

Task 2: A health facility has outreach activity four days per month to vaccinate a target population of 2500 infants in the 0–11 month age group. For outreach activity freeze-sensitive vaccines are placed in cold boxes and other vaccines are placed in vaccine carriers. What measures are required to ensure end-to-end temperature monitoring for this outreach activity?

Task 3: Vaccine is shipped from a supplier to a country having a central store with 11 cold rooms (which includes two freezer rooms). The supplied vaccines are then distributed by air to 45 regional cold rooms for storage prior to eventual transfer to districts with vaccine refrigerators and ice pack freezers. Are temperature monitoring devices required during transport of vaccines from the supplier to the central store and from the central store to the regional stores to ensure end-to-end monitoring? If so, what would be the specification and quantities of these devices?

5.2.3 Arranging vaccines in refrigerators

Vaccines should be arranged in such a way as to facilitate air circulation and the reading of their identification and expiry date. Hence, vaccines whose expiry date is closest will be used first (EEFO principle). Vaccines whose expiry dates have passed should not be preserved. Opened and partially used vials of vaccines that satisfy the opened vial policy requirements brought back from a vaccination session should be marked with a sign and arranged separately. They will be used first. The refrigerator with vaccines should only be opened in case of necessity. Leaving the refrigerator open for too long must be rigorously avoided.

Note: Label all equipment in the vaccine store to indicate the content (type of vaccine, batch number, expiry date). These labels will facilitate the search for vaccines to be delivered and help to avoid unnecessary opening of equipment.

The arrangement of vaccines in the refrigerator should follow the general storage guidelines given above. The arrangement will also depend on the type of cold chain equipment.

Figure 5.4 Vaccine handling in a vertical refrigerator

The arrangement procedure for a vertical refrigerator is as follows:

- The YF, OPV, measles and BCG vials should be arranged on the highest shelves, close to the freezing compartment.
- The Penta, DTP and TT/Td vials will be kept on the middle shelf away from the freezing compartment. Diluents for BCG, measles and YF will also be arranged near the Penta, DTP and TT/Td vials.

Figure 5.5 Vaccine handling in a chest refrigerator

The vaccines should always be arranged in the baskets provided for that purpose.

- The YF, OPV, BCG and measles vaccine vials should be packed in the lower section of the refrigerator's compartment, above the reserve ice packs.
- The Penta, DTP and TT/Td vials should be arranged in the upper basket, away from the bottom where they may be exposed to freezing temperatures. The diluents for BCG, measles and YF will also be stored near the Penta, DTP and TT/Td vials.

5.2.4 Preparing vaccines for transportation

Due to the high risk of freezing for some vaccines, transportation of vaccines should consider the following:

- Freeze-sensitive vaccines to be packed with conditioned or cold water packs.
- Non-freeze-sensitive vaccines to be packed either with frozen packs separately from freeze-sensitive vaccines or with conditioned or cold water packs.

If conditioned packs are used for transportation of freeze-sensitive vaccines, a freeze indicator should be placed in each cold box/vaccine carrier. How to condition frozen packs:

- Remove the frozen packs from the freezer and let them defrost at room temperature.
- Shake frequently until you can hear water inside the pack.
- Place in the cold box/vaccine carrier.

5.2.5 Safekeeping vaccines during immunization sessions

The importance of preserving vaccines during immunization sessions cannot be over emphasized. Because vaccines are very sensitive to heat and light, the following principles and guidelines must be strictly adhered to during immunization sessions:

- The actual vaccination must be done in the shade.
- Antigen vials must be taken out one at a time.
- The vaccine carrier must remain closed throughout.
- Open vials (including reconstituted vaccines) must not be placed on top of ice packs. Use the foam pad on the top of the vaccines carrier instead.
- Vaccine vials must not be placed in a bowl with water and/or ice. This causes labels and VVM to come off.
- Vaccines should be reconstituted in the presence of the person to be vaccinated with appropriate diluents in sterile conditions.
- Follow the septic requirements when administering vaccines.
- Water packs that are unfrozen/warm must not be returned to the vaccines carrier with vaccines.

5.2.6 Shake test: Method for testing frozen vaccine vials

By shaking the vial it can be easily established whether TT/Td, DT DTP/HepB/Hib liquid and PCV vaccines were frozen or not. When any of these vaccines is suspected to have been frozen, it is recommended to apply a shake test as follows:

1. Prepare a frozen control sample: Take a vial of vaccine of the same type and batch number and from the same manufacturer as the vaccine you want to test. Freeze the vial until the contents are solid, (at least 10 hours at -10°C) and then let it thaw. This vial is the control sample. Mark the vial clearly so that it is easily identifiable and will not be used by mistake.

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

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

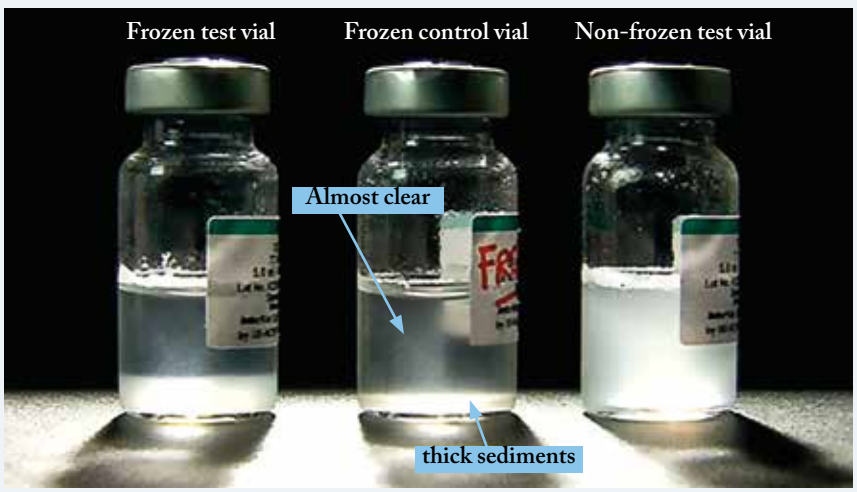
4. Allow to rest: Leave both vials to rest.

5. Compare the vials: View both vials against the light to compare the sedimentation rate. If the test sample shows a much slower sedimentation rate than the control sample, the test sample has most probably **not been frozen** and can be used. If the sedimentation rate is similar and the test sample contains flakes, the vial has probably been damaged by freezing and **should not be used**.

Note: Some vials have large labels which conceal the vial contents. This makes it difficult to see the sedimentation process. In such cases, turn the sample and reference vials upside down and observe sedimentation taking place in the neck of the vial.

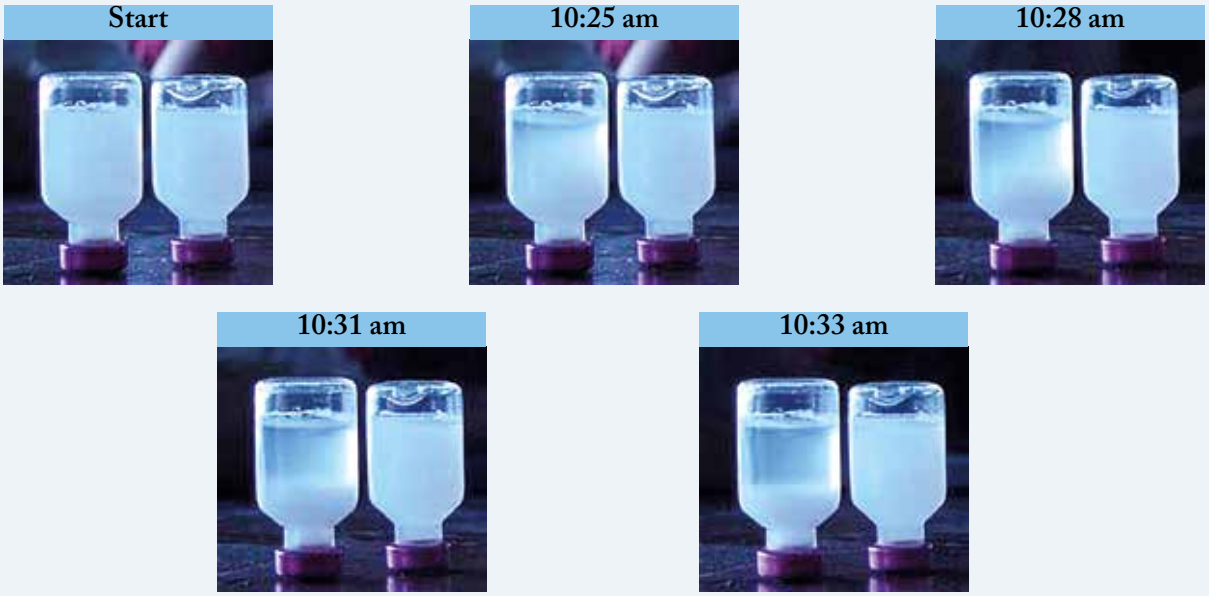
If the test procedure indicates that the test sample has been damaged by freezing, you should notify your supervisor immediately. Standard operating procedures should then be followed to ensure that all damaged vaccine is identified.

Figure 5.6 Reading the shake test results



If the sediments in the suspect vial settle slower than the control vial, then the vaccine in the suspect vial has not been damaged by freezing and **can be used**

Figure 5.7 Shake test images



5.3 Storage, transport and handling of diluents

The most frequently used diluents are those for BCG, measles, MR, MMR, yellow fever and meningitis vaccines.

- Diluents from different suppliers and for different vaccines should not be interchanged, because they might contain different components. It is a requirement that vaccines, must always be accompanied by **diluents from the same supplier.**
- Diluents can be stored in a depot adjacent to the cold chain and do not need to be kept at cool temperatures until the day before they are due for use. **At service delivery, diluents should be kept in cold chain.**
- Liquid temperature sensitive medicines must be properly labelled before they can be stored in the fridge with vaccines. For instance, products like insulin can easily be mistaken for a vaccine diluent if not properly labelled. When vaccines are reconstituted with insulin or other unsuitable products, the end result could be lethal for the vaccinated person.
- Reconstituted vials should be discarded at the end of the immunization session or after six hours whichever comes first.
- Biological specimens and other infectious substances (stools specimens and body fluids) should not be kept in the fridge with vaccines. If needed, they can be stored temporary at the facility using appropriate passive containers with coolant packs.
- It is strictly forbidden to keep drinks and foods in a fridge for vaccines.

It is dangerous to keep reconstituted vaccines beyond the recommended time or for the following day.

5.4 Organizing vaccine distribution

The efficiency of a vaccine distribution system depends on adequate transportation system, proper documentation and budgeting. It also depends on the regular effective supervision. A proper documentation of vaccine stocks and flow is key to the effective monitoring of immunization activities. The system needs minimum requirements as follows:

- vaccine stock registers with columns for batch number, manufacturer, expiry date, stock balance, origin and destination, etc.)
- vaccine requisition/issuing forms
- supervision register
- cold chain maintenance register
- distribution plan
- session plan at delivery point

5.4.1 Requisition vouchers

A vaccine requisition voucher should, as a minimum, include the following elements:

- reference number of the order/requisition
- minimum/maximum stock levels for each vaccine and diluents
- stock in hand for each vaccine and diluents
- quantities requested for each vaccine and diluents
- where syringes, needles and safety boxes are supplied with vaccines they should be included in the form
- name and signature of EPI manager (the person issuing the order).

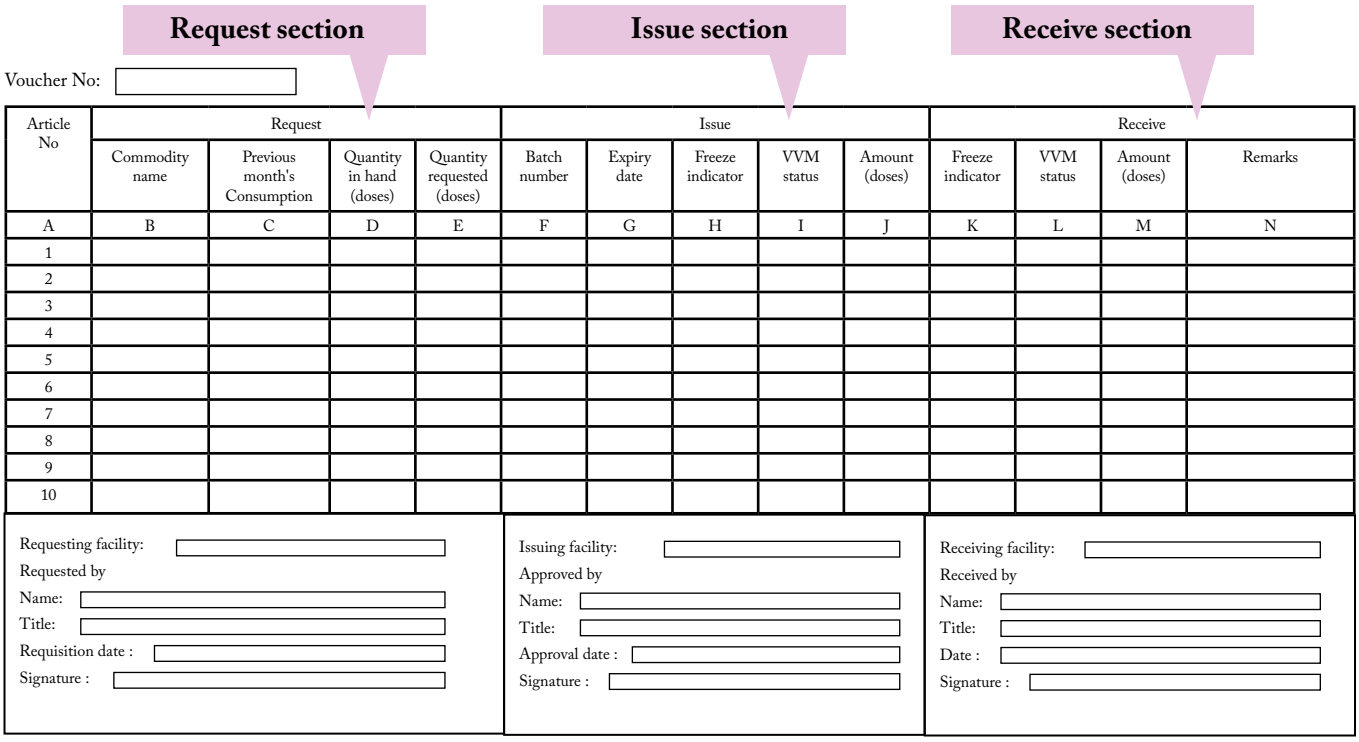
5.4.2 Issuing forms

- number or reference of the order form
- number or reference of issuing form (where it is separate from requisition form)
- quantities requested for each vaccine, diluents and safe injection material
- quantities delivered for each vaccine, diluents and safe injection material
- presentation (doses/vial)
- batch number, expiry dates and manufacturer for each vaccine delivered.

The issue form should be issued in two copies. The original will accompany the consignment and serve as delivery voucher to acknowledge receipt at destination.

The copy will be recorded by the vaccine store manager in the register and archived. Requisition and issue vouchers can be single ledger in triplicate.

Figure 5.8 Model order form



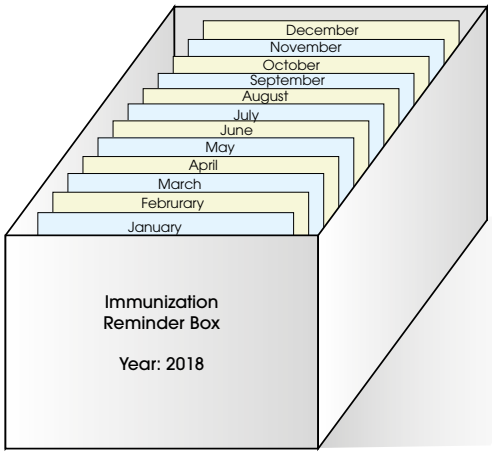
Exercise 6

For all groups.
Participants should design a model order form and a model delivery form, adapting them to their own situation. Discussions on the proposed formats in the group should follow to identify the strong points and weaknesses in the forms.

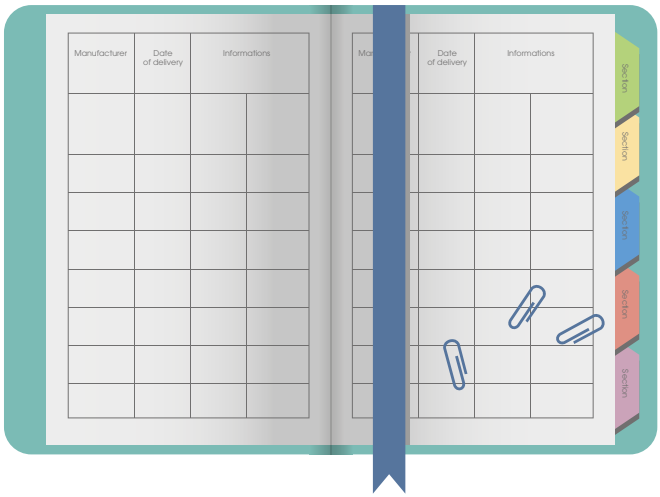
5.5 Inventory management and recording transactions

In stock management, all movements of stocks should be recorded for both transparency and traceability. The stock recording can be organized in different ways according to the administrative level:

- **At the store as a working document for the storekeeper:** Individual stock sheets are used for each batch of vaccines. These individual sheets for batches of the same antigen will be filed in a single folder with the name tag of the given antigen.



- **At all vaccine storage levels:** A single register can be used to record all movements of vaccine stocks. From central to lowest distribution level a vaccine register composed of two sections could be used: one for the general reception/ entry of all vaccines and another one for requisition issues for individual vaccines.



At the national and subnational stores, a computerized vaccine management system is more appropriate and should be used in combination or replace the manual system. Different software applications are available and can be adopted by countries upon accessibility. A simple MS Excel-based computerized stock management tool (SMT) is available from WHO.

5.5.1 Templates for manual recording of stock transactions

Vaccine stock cards or registers are the main manual recording tools used in the store. They should be kept with the vaccines in the same premises (or nearby). An individual stock card will be kept for each batch of vaccines to record all the transactions of the batch. Individual stock cards for batches of each vaccine will be filed in a single folder with the name tag of the vaccine. A stock summary sheet will be created to aggregate the stock for all batches of each vaccine. A vaccine file will therefore be composed of individual batch cards of that vaccine.

Individual batch card template

Each individual batch card contains the following information:

- **Heading indicating:**
  - name of the vaccine
  - batch number
  - expiry date
  - manufacturer
  - presentation (number of doses per vial).
- **Table with the following columns:**
  - date of the transaction
  - origin (for incoming), destination or purpose (for outgoing)
  - quantity received (arrival, returns from the lower levels, excess from physical count)
  - quantity issued (dispatch, loss adjustment, missing from physical count)
  - stock balance
  - remarks and observations.

Figure 5.9 Example individual batch card

VACCINE BATCH CARD

VACCINE:	OPV

BATCH No:	DATE OF EXPIRATION	MANUFACTURER	PRESENTATION OF VACCINE
P-432J	May-17	Chiron	20 doses per vial

DATES	ORIGIN / DESTINATION OR UTILIZATION	QUANTITIES (vials)		BALANCE (vials)	OBSERVATIONS COMMENTS
		RECEIVED	ISSUED		
01-Mar-15	UNICEF	600		600	
25-Mar-15	Tala		20	580	
30-Apr-15	Kala		30	550	

Vaccine stock summary sheet

A vaccine stock summary sheet is created for each vaccine to present the overall situation of all batches received to date. The content of this vaccine stock summary sheet includes the following:

- **Heading with:**
  - name of the vaccine
  - critical stock levels (min/max and reorder)
  - date of the update.
- **Table with the following columns:**
  - date of reception of batch
  - batch number
  - expiry date
  - presentation (number of doses per vial)
  - quantity received
  - quantity issued
  - stock balance of the current batch
  - total stock balance of the vaccine
  - storage location in the cold chain.

Figure 5.10 Example vaccine stock summary sheet

VACCINE SUMARY CARD

Critical stocks (doses)		
Reserve	Re-order	Maximum
25,000	30,000	125,000

VACCINE	OPV

MONTH:	MAY	YEAR:	2017

DATES		BATCH No:	Presentation doses/vial	QUANTITIES (vials)		Stock balance per batch (vials)	Stock balance total (doses)	STORAGE LOCATION
Reception	Expiry			RECEIVED	ISSUED			
01-Mar-15	May-17	P-432J	20	150	50	100	2,000	Freezer 3
01-Mar-15	Jun-17	P-432R	10	100	-	100	1,000	Freezer 3
TOTAL							3,000	

Exercise 7

Ask each participant to design a model vaccine stock sheet for the intermediate and peripheral levels. Discuss the proposals in the group and identify strong points and weaknesses.

Vaccine stock registers

Vaccine stock registers are booklet format, designed to record in a single table all transactions of the same vaccine. Dividers can be inserted to identify dedicated section per vaccine. The vaccine stock register will contain the following information (see Figure 5.11):

- name of the vaccine
- critical stock levels (min/max and reorder)
- date of transactions
- origin/destination
- purpose of the operation (NID, campaign, epidemic control, etc.)
- batch number
- expiry date
- quantities received
- quantities issued
- stock balances:
  - stock balance for the current batch
  - total stock balance of the antigen
- remarks and observations.

Figure 5.11 Example vaccine stock register page

VACCINE
OPV

Critical Stocks doses	Reserve	Re-order	Maximum
	10,000	12,500	25,000

DATES	ORIGIN DESTINATION	Number of vials Identification of the vaccine				Presentation (dose/vial))	Stock balance per batch (doses)	Stock balance total (doses)	Observations remarks
		Received	Issued	Batch No.	Expiry date				
02-Jan-15	C/F	500		4-A	30-Apr-17	10	500	5,000	
02-Jan-15	C/F	50		9-G	30-Jun-17	20	50	6,000	
07-Jan-15	HF Kala (district Yala)		9	4-A	30-Apr-17	10	491	5,910	
07-Jan-15	HF Kala (district Yala)		10	9-G	30-Jun-17	20	40	5,710	WM(2)
02-Feb-15	Received	500		3-F	30-Jun-17	20	500	15,710	Nids
31-Mar-15	Missing from inventory		4	4-A	30-Jun-17	10	487	15,670	
31-Mar-15	Excess from inventory	2		9-G	30-Jun-17	20	42	15,710	

Exercise 8

Ask each participant to design a model vaccines movement register for the intermediate and peripheral levels. Discuss the proposals made by the group.

5.6 Physical count of vaccine stocks

The physical count should be conducted in all vaccines stores. The periodicity of the physical count will depend on the frequency of vaccine supplies. Generally, it varies between one to six months. The physical count should be done for each batch. The real stock should be recorded in the stock register/card by adjusting number of doses missing or in excess. A sample of vaccine physical count form is shown in Figure 5.12.

Figure 5.12 Example stock physical count form

VACCINE STOCK COUNTING FORM

VACCINE _____ DATE : _____ COUNTED BY : _____

ROOM/DEVICE : _____ SUPERVISED BY : _____

BATCH No	EXPIRY DATE	BOXES No	VIALS per BOX	VIALS in OPENED BOX	VIAL SIZE	TOTAL		
						DOSES COUNTED	DOSES ON STOCK CARD	DIFFERENCE (Doses)
TOTAL								

The vaccine stock records should be adjusted following the results of the physical count. The following stock adjustments are recommended:

For registers:

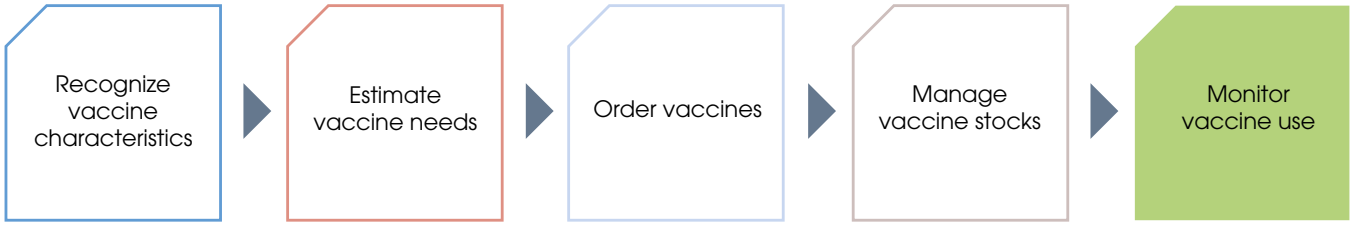
- If the actual quantity from the physical count is more than the theoretical stock in the records, the difference should be recorded under received/arrival (incoming stocks) and indicated as "excess" or "surplus" in the affiliation of origin column.
- If the actual quantity from the physical count is less than the theoretical stock, the difference should be recorded under issued (outgoing stocks) and indicated as "missing" in the affiliation of destination column.

For individual batch sheets:

- If the actual quantity from the physical count is more than the theoretical stock in the records, the difference should be recorded under received/arrival (incoming stocks) and indicated as "excess" or "surplus" in the origin/destination column.
- If the actual quantity from the physical count is less than the theoretical stock, the difference should be recorded under issued (outgoing stocks) and indicated as "missing" in the origin/destination column.

Exercise 9

Optional.
Ask each participant to update the different management tools after taking a physical inventory of vaccine stocks.
Discuss the proposals in a group.



6. Monitor vaccine use

Each programme manager must ensure that the following vaccine management and utilization policies are adopted and effectively implemented:

- The use of the vaccine vial monitor.
- The application of the policy of the opened/partially used vaccine vial.
- Monitoring the utilization and wastage of vaccines.

6.1 What is a vaccine vial monitor?

The accumulated exposure of vaccines to heat can now be monitored with the VVM, placed on the vaccine vial.

- A VVM is a label containing a heat-sensitive material which is placed on a vaccine vial to register cumulative heat exposure over time.
- The combined effects of time and temperature cause the inner square of the VVM to darken, gradually and irreversibly. A direct relationship exists between the rate of colour change and temperature.

The VVM is a square placed within a circle and is sensitive to heat (Figure 6.1). If after being exposed to heat for a period of time the square takes the same colour or becomes darker than the circle, the vial should be discarded. Figure 6.2 explains how the VVM works.

Figure 6.1 VVM

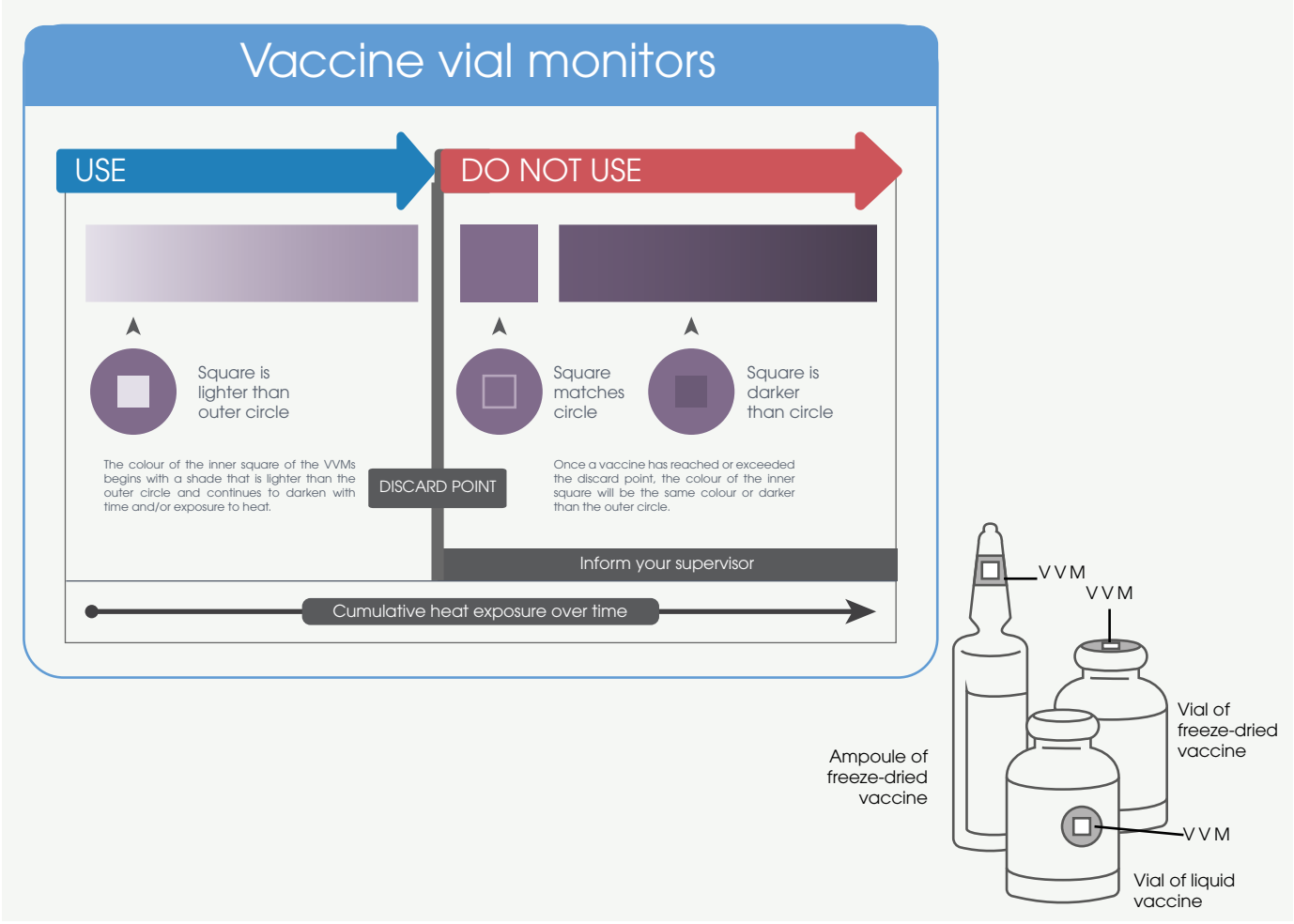
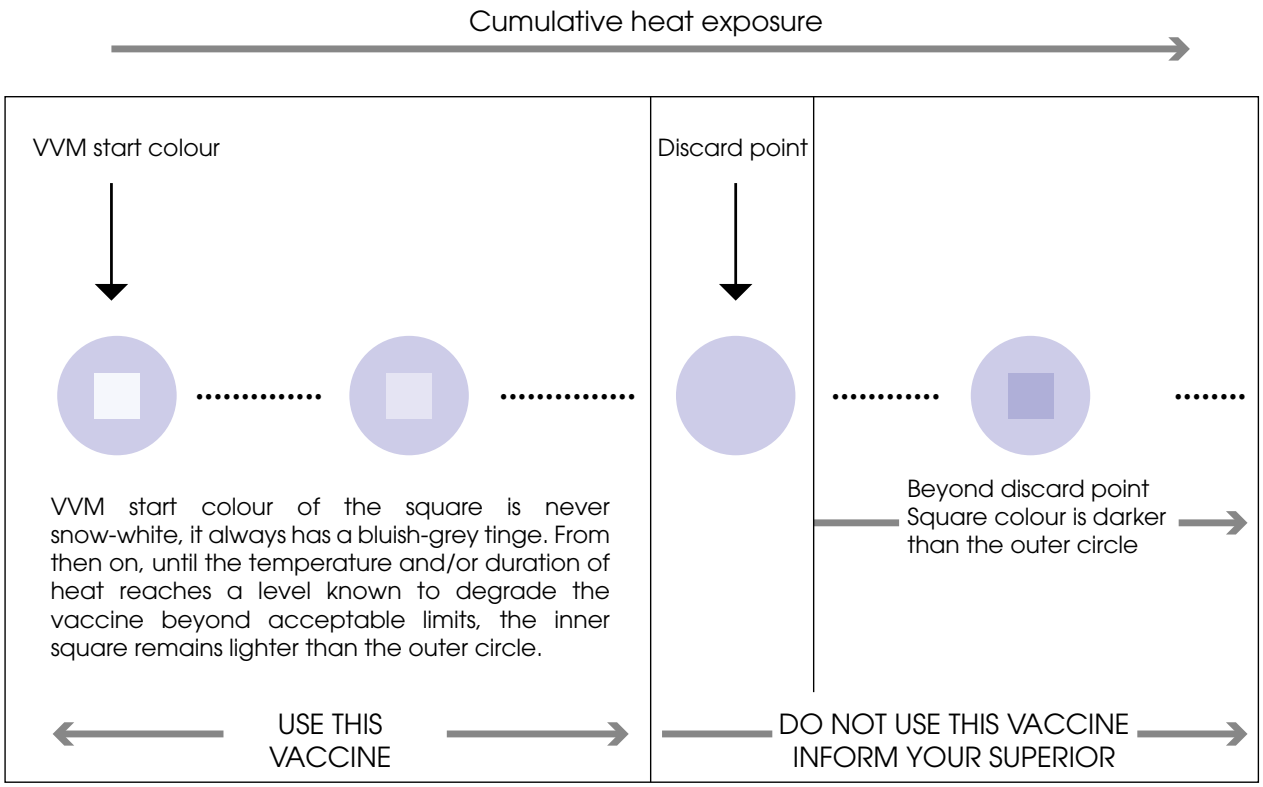


Figure 6.2 The impact of cumulative heat exposure on the VVM



There are different types of VVMs, all of them using the same principle but using different time periods for the colour change.

Table 6.1 VVM reaction rates by category of heat stability

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

Note: VVM (Arrhenius) reaction rates are determined at two temperature points.

Same vaccines from different manufacturers may be assigned to different categories due to different stability data. Example the DTP-HepB-Hib from one manufacturer could have VVM14 whilst the DTP-HepB-Hib from another manufacturer could have VVM7.

Examples where VVM could be used as a daily management or decision-making tool

The VVM may be used to reduce vaccine wastage and identify problems or breakdowns in the cold chain.

The VVM enables the user to determine at any time whether a vaccine vial can still be used despite possible disruptions in the cold chain.

The vaccine may be used without any risk outside the cold chain until the VVM reaches the discard point. The period of use will depend on the ambient temperatures and the quality of the cold chain.

Vaccine vials least exposed to heat, as evidenced by VVM colour changes, can be sent to distant outreach posts conducting vaccination campaigns or remote areas with fewer vaccination sessions.

Vaccine vials with VVM close to the discard point must be used immediately or be sent to health facilities where they can be used quickly.

The elimination of large quantities of vaccine because of the VVM colour change to discard point may lead to a survey on the cold chain. The data may also be used to take decisions on the choice of appropriate cold chain equipment.

Health workers and stock management officers may refrain from declaring that the VVM reached the discard point for fear of being reprimanded for the ignorance that caused substantial vaccine wastage. Based on the VVM's status, health and administrative staff can take appropriate corrective measures.

Repeated misuse of this valuable tool by health workers or vaccine management staff can indicate the need for staff training in cold chain.

6.2 Multi-dose vial policy (MDVP)

An opened multi-dose vial is a vial containing several doses of vaccine from which one or more doses have been taken. To ensure the optimal use of vaccines, WHO has issued policies end guidance documents authorizing the re-use, "under certain conditions".

6.2.1 What is the WHO multi-dose vial policy?

All opened WHO-prequalified multi-dose vials of vaccines should be discarded at the end of the immunization session or within six hours of opening, whichever comes first, unless the vaccine meets all four of the criteria listed below. If the vaccine meets the four criteria, the opened vial can be kept and used for up to 28 days after opening. The criteria are as follows.

1. The vaccine is currently prequalified by WHO.
2. The vaccine is approved for used up to 28 days after opening the vial, as determined by WHO.
3. The expiry date of the vaccine has not passed.
4. The vaccine vial has been, and will continue to be stored at WHO- or manufacturer-recommended temperatures; furthermore, the vaccine vial monitor, if one is attached, is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing.

For vaccines that are not prequalified by WHO, independent determinations on preservative efficacy, sterility, presentation and stability may not have been made by a functional national regulatory authority. Consequently, this could mean that the vaccine does not meet the WHO requirements on safety and efficacy, which form the minimum recommended standard for keeping multi-dose vaccine vials opened for more than six hours. Therefore, WHO recommends using non-WHO-prequalified vaccines as soon as possible after opening, and respecting the time limit for using opened vials as indicated by the manufacturer's instructions in the package insert. If this information is not indicated in the package insert, WHO recommends discarding all non-WHO-prequalified vaccine products within six hours after opening or at the end of the immunization session, whichever comes first.

If the expiry date has not elapsed, then one should look for damage caused by heat, cold or contamination. Before applying the MDVP, safe injection practices should be in place. This policy applies equally to all opened vials of vaccine to be used during outreach strategy or mass vaccination campaigns on conditions that standard procedures required for handling these vials are strictly followed. The direct impact of MDVP in the field may be a substantial reduction of wastage for liquid vaccine with preservative.

6.2.2 Location of VVM

The WHO vaccine prequalification programme has worked with vaccine manufacturers to define VVM placement guidelines so that the VVM, if attached to the vial, can serve as a visual trigger to assist a health worker in properly applying the MDVP. There are two different locations for VVMs and each is associated with specific guidance for handling opened multi-dose vials of vaccine.

1. WHO-prequalified vaccines where the VVM, if attached, is on the label of the vaccine. The vaccine vial, once opened, can be kept for subsequent immunization sessions for up to 28 days, regardless of the formulation of the product (liquid or lyophilized).

2. WHO-prequalified vaccines where the VVM is attached in a different location than on the label (e.g. cap or neck of ampoule). In this instance, the vaccine vial, once opened, must be discarded at the end of the immunization session or within six hours of opening, whichever comes first. This is regardless of the formulation of the product (liquid or lyophilized) and would apply, for example, to a reconstituted product of which the vaccine vial cap, which has a VVM attached, has been discarded after opening.

6.3 Monitoring vaccine use and wastage

Monitoring the use of vaccines is a priority activity for the immunization manager. This will ensure the quality of immunization services and keep the vaccine wastage under control. The goals of monitoring are two-fold:

- To detect management problems during vaccine use at different levels and find appropriate solutions.
- To contribute to the EPI planning by providing data on vaccines needs and vaccines wastage rates.

6.3.1 What is vaccine wastage?

It is important that the managers understand and are able to explain clearly to other health staff under their supervision what vaccine wastage is in order to avoid misinterpretations leading to inappropriate actions. There are generally two concepts[10] of vaccine wastage (see Table 6.2).

While the doses sacrificed in the course of good practice vaccination (good reasons) should be minimized, doses wasted without purpose must be avoided!

Table 6.2 Vaccine wastage – lost and sacrificed doses

Vaccine doses lost for no good reason	Vaccine doses sacrificed for good reason!
Doses wasted for no good reason are essentially unopened vials or opened vial wastage. These are: • Unopened vials that have expired, damaged or suffered from excessive heat exposure, freezing or improper handling. • Losses due to poor implementation of the MDVP: discarding opened vials of vaccines eligible for reuse because of misuse/misinterpretation or ignorance of the MDVP. • Losses due to non-adherence to national immunization schedule leading to incorrect administration of doses, at wrong age and with wrong interval between doses.	Doses sacrificed for good reason can be only opened vial wastage. These are: • Doses discarded from opened vial in accordance with the MDVP, i.e. reconstituted vaccine or liquid vaccine with no preservative at the end of session or in line with MDVP (e.g. after four weeks). • Administration of vaccines to persons outside target age group.

10 Souleymane Kone. Notes d'informations sur les pertes de vaccines (WHO/ICP/Abidjan, 2002, WHO/HQ, 2015).

Exercise 10

For all groups.
Discuss in small groups and classify the following vaccine loss in "lost doses" or "sacrificed doses":

- doses of BCG administered to children aged four years
- doses of frozen DTP vials
- doses in expired vials
- doses of TT administered to the informal sector
- OPV vials with VVM reached discard point
- Penta vaccine doses administered in two-week interval between doses
- Penta vaccine doses administered with a 23-day interval between doses
- measles vaccine from a 20-dose vial used only for two children
- opened OPV vials thrown away at the end of vaccination sessions
- opened yellow fever vaccine vials thrown away after six hours.

This exercise deserves a plenary presentation – prepare for it!

6.3.2 Vaccine wastage and usage rates

Sound vaccines management should endeavour to avoid vaccine losses and minimize sacrificed doses. This can be achieved only when the use of vaccines is monitored efficiently. The two indicators for monitoring vaccine use are: **vaccine wastage rate (VWR) and vaccine usage rate.**

Vaccine wastage rate: The quantity of vaccine taken from the inventory, but not administered to the target population is the total amount of lost and sacrificed doses. Depending on whether one is a supervisor or user, monitoring vaccines wastages rate can be both simple and tedious.

At user level the calculation of vaccine wastage rate is relatively easy. It can be presented in graphical form in the same way as a vaccination coverage monitoring chart, plotted at each facility.

The vaccine wastage rate is calculated for each vaccine. For one vaccine, the wastage rate is calculated by considering the total doses from the different presentations (1, 2, 4, 5, 6, 10 or 20 doses) used in the programme.

Vaccine wastage should be calculated and monitored according to their typology: unopened/closed vial wastage and opened vial wastage. Monitoring vaccine wastage by typology relates to the causes of the wastage and the results will help solving any underlined problems.

1. Unopened/closed vial vaccine wastage formula

The unopened vial wastage within a given time period is calculated using the following formula:

$$\textbf{Wastage}_{\text{unopened vials}} = [\Sigma^{n}\textbf{Doses}_{\text{wasted}} / \Sigma^{n}\textbf{Doses}_{\text{supplied}}] \times 100$$

Where: $\Sigma^{n}\textbf{Doses}_{\text{wasted}}$ = Cumulative doses of unopened vials discarded from the inventory
$\Sigma^{n}\textbf{Doses}_{\text{supplied}}$ = Cumulative total number of vaccine doses supplied

Unopened vial wastage should be calculated during each physical inventory!

The successful implementation of effective vaccine management practices will avoid unopened vial vaccine wastages. Proper vaccine stock monitoring should be established for early detection of risk of unopened/closed vial wastage so anticipated corrective actions can be taken.

Note: Effective vaccine management (EVM) limits to 1% the unopened vial wastage per storage facility and, subsequently, per supply chain level. The maximum unopened vial wastage should be considered while estimating vaccine needs for the immunization programme. Each national immunization programme should establish a system for recording and reporting unopened vial wastage.

2. Opened vial vaccine wastage formula

The wastage in opened vials within a given time period is calculated using the following formula:

$$\textbf{Wastage}_{opened} = [(\sum^{n}\textbf{Doses}_{opened} - \sum^{n}\textbf{Doses}_{administred})/ \sum^{n}\textbf{Doses}_{opened}]$$

Where: $\sum^{n}\textbf{Doses}_{administred}$ = Cumulative doses administered to the target population
$\sum^{n}\textbf{Doses}_{opened}$ = Cumulative number of doses of the vaccine vials opened for vaccination

Opened vial wastage can occur only at the service delivery point with multi-dose presentations. These are unavoidable wastages. Undue pressure on health workers to reduce wastage may push them to erroneously refrain from opening multi-dose vials when the number of children is insufficient. This can lead to a reduction of coverage and must be avoided. National immunization programmes should monitor opened vial wastage with the vaccination coverage. Regular monitoring of opened vial wastages will stimulate proper planning and management of services and contributes to eliminate the unfounded fear of wastage that may affects coverage.

Note: There are no maximum wastages established globally for opened vial wastage. Doses discarded with multi-dose vials may be high depending on the vial size, the status of MDVP, local setting and type of vaccination service delivery. With the cost of vaccines increasing, programme managers need to take the required action to reduce vaccine wastage rates to an absolute minimum without comprising efforts to protect children.

3. Performance of immunization services – coverage and wastage targets

The vaccine wastage rate is a performance indicator of the immunization services. Each national immunization programme should establish its own wastage targets to be achieved and maintained. Four classes[11] of performance combining coverage and wastage targets are suggested to guide the monitoring of the utilization of vaccines in national immunization.

Class A: Health facilities and districts achieving and maintaining both coverage and wastage targets. These are high-performing facilities and districts with efficient utilization of vaccines.

Class B: Facilities and districts achieving and maintaining coverage targets with wastage higher than expected. These are high-performing health facilities and districts albeit with high wastage rates.

Class C: Facilities and districts that are not reaching the target coverage, although the wastage is lower than expected. These are low-performing health facilities and districts with low wastage rates.

Class D: Health facilities or districts not achieving coverage or wastage targets. These are poorly performing facilities and districts.

Annex 4 gives an example showing how the above classification was used in one of the country in the African Region with suggestions to improve vaccine management and utilization practices. The targets for both vaccination coverage and wastage should be considered dynamic – as immunization programmes evolve. Originally established programme targets should be adjusted to reflect changing context. And thus, the distribution of facilities and districts across vaccine utilization performance classes should be adjusted accordingly.

11 This classification was proposed by Dr Clément Glèlè Kakai, national immunization officer (EPI/Benin) and Dr Mary Traoré, Inter-country logistics officer (AFRO/IST West Africa). This classification is currently adopted and used in the DVD-MT to monitor performance of national immunization service delivery.

6.4 Vaccine management report

Periodic vaccine management reporting should occur at each level of the cold chain as prescribed by the EPI manager. A vaccine management report should be integrated into the facility's monthly report. The vaccine management report should highlight, for a given period, the overall situation on:

- **Inventory of vaccines and supplies (details for each vaccine, diluents and safe injection equipment):**
  - quantity in stock at the beginning of the period for each batch
  - quantity received during the period
  - quantity in stock at the end of the period for each batch
  - number of days of stock availability (stock-out or over-stocking for each vaccine, diluents and safe injection equipment).

- **Status of distribution of vaccines and supplies to recipients:**
  - quantity distributed per month
  - total quantities distributed by destination since the beginning of the year
  - coverage for reporting period and cumulative coverage of achievement or rate of vaccine use by recipient.

Based on the above data, the stock management officer prepares **a narrative report** (one to two pages) indicating:

- Vaccines available for immunization activities (quantities in stock and consumption period to be covered).
- Stock-outs or over-stocking of vaccines, according to the established minimum and maximum stock levels.
- Vaccines status at reception and distribution (VVM, cold chain monitoring indicators, etc.).
- Cold chain performance (number of days with inadequate temperature, number of days of breakdown, etc.).

Vaccine management performance is measured by:

- Vaccine storage quality:
  - storage temperatures, including temperature alarms
  - cold chain storage capacity
  - cold chain infrastructure, equipment and transport
  - cold chain maintenance.
- Vaccine stock management.
- Efficient vaccine shipment and distribution.
- Proper use of diluents.
- Correct utilization of VVM.
- Correct use of MDVP.
- Reduction of vaccine wastage.

The above periodic report on vaccine management should be submitted to the EPI manager. It will be used as an EPI management tool to facilitate not only the follow-up and control of vaccine stock; but also to monitor the implementation of immunization activities. The analysis of the report should enable the programme to identify, on time, potential problems (imminent danger of shortages or expiry, interruption or slowdown of activities, wastage, etc.) and suggest appropriate solutions. It is important to give feedback on the report, which should include what support could be given from the upper level or the immediate supervisor. Periodic EVM assessments will assist the EPI manager in measuring progress and identifying recurrent problems in vaccine management.

Recommended reading

PATH/WHO (2013). Optimize. Delivering vaccines: A cost comparison of in-country vaccine transport container options. Seattle (WA): Program for Appropriate Technology in Health; Geneva: World Health Organization.

WHO (2005). Monitoring vaccine wastage at country level: Guidelines for programme managers. WHO/V&B/03.18. Rev.1. Geneva: World Health Organization.

WHO (2008). Training for mid-level managers (MLM). 1. Cold chain, vaccines and safe-injection equipment management. WHO/IVB/08.01. Geneva: World Health Organization. [check if need this]

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). 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). Mid-level management course for EPI managers. Module 7: Cold chain management. Brazzaville: World Health Organization Regional Office for Africa.

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).

Websites

WHO – Immunization, Vaccines and Biologicals (Vaccine position papers):
http://www.who.int/immunization/documents/positionpapers/

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: Vaccine arrival report (VAR)

Guidelines for completing the vaccine arrival report
The vaccine arrival report (VAR) is a comprehensive record of cold chain conditions during transport and of compliance with shipping instructions. Recipient governments, UNICEF country offices and the UNICEF Supply Division are responsible for the report and for taking appropriate action if problems are reported (e.g. follow up with the manufacturer, forwarding agent, WHO, etc.).

Use one report form for each shipment and for each vaccine in the shipment: In shipments containing diphtheria-tetanus-pertussis (DTP)-hepatitis B (HepB) and Haemophilus influenzae type b (Hib) vaccines, use one form for DTP-HepB and a separate form for Hib. In the case of short shipments (where parts of the original quantities are not delivered), complete a separate report for each part delivered.

Complete the form as described below. In the header boxes at the top of the form, enter the name of recipient country, report number and details of place and date of inspection and storage. The report number is an internal number for organizing records and is compiled as follows: country code-year-number for each report (e.g. BUR-2005-001 for one vaccine; BUR-2005-002 for a second vaccine etc.). In the case of a short shipment, the numbers for the separate deliveries would be, for example, BUR-2005-003.1, BUR-2005-003.2 etc.

Part I: Advance notice
I.1 Enter dates and details of documents received in advance of the vaccine shipment.

Part II: Flight arrival details
II.1 Fill in details of expected and actual arrival times for the shipment.
II.2 Fill in the names:
a) of the clearing agent
b) for whom the agent acts (e.g. the ministry of health or UNICEF).

Part III: Details of vaccine shipment
III.1 Fill in details of the order (purchase order number, consignee, vaccine description etc.).
III.2 For each batch of vaccine included in the shipment, record:
a) number of shipping boxes
b) number of vials
c) expiry date.

The number of boxes you enter should always match the number of boxes shown in the packing list. If it does not, note (under Comments) if advance notice of a change in the quantity was provided. It is not necessary to count the number of individual vaccine packs in each shipping box for this report.
III.3 For the diluents and droppers (if included) with each batch of vaccine in the shipment, record:
a) number of shipping boxes
b) number of vials
c) expiry date.

The information for III.2 and III.3 is also in the packing list.
Note: Diluents for freeze-dried vaccine and droppers for or a polio vaccine (OPV) are integral parts of the vaccine, so always include them on the same form. If diluent/droppers are delivered separately, consider it a short shipment.

Part IV: Documents accompanying shipment
The packing list should indicate which box contains the shipping documents (usually Box 1).
IV.1 If this information is not included in the packing list or in documents sent separately by courier, pouch or other means, note this under Comments.
IV.2 Verify that all necessary documents are present and complete the form accordingly.
Note: If the lot release certificate is missing, do not use the vaccines; keep them on hold in cold storage until the relevant document has been obtained from the vaccine manufacturer.

Part V: Status of shipping indicators

Inspect the temperature monitors in all boxes before putting vaccines into cold storage. For very large shipments or when immediate storage in the shipping boxes is required, check a representative number of boxes before placing the shipment in the cold store. Complete inspection of all boxes the next day, or as soon as possible thereafter; under Comments, note the date and time when the complete inspection took place.

Note: In this report, enter the information below (V.1) only for boxes in which the temperature monitors how a change that indicates potential damage to vaccines (vaccine vial monitor stages 3 and 4, cold chain monitor card as per vaccine/threshold table in card, or alarm indication in the electronic device).

V.1 Enter:

a) number of boxes inspected (this should equal the total number in the shipment)

b) type of coolant used

c) details of any temperature exposure, if detected.

V.2 Photocopy or scan LCD screens in electronic devices that show alarm status and attach to report.

V.3 Clearly identify vaccines in boxes in which the indicators show exposure to temperatures that risk damage and keep them in the cold room for further assessment of their condition. Do not discard vaccines until assessment is completed.

Part VI: General conditions of shipment

VI.1 Indicate if the shipping boxes were received in good condition and if all necessary labels on the outside of the shipping boxes were present; add any comments.

Part VII: Name and signature

VII.1 The authorized person responsible for the inspection and the central store manager or the EPI manager should sign this report.

VII.2 Send the form, completed and signed, to the UNICEF country office within three days of arrival of the vaccine; they will forward it to the UNICEF Supply Division (Immunization Team, Fax: +45 35269421).

Vaccine Arrival Report (VAR)

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

COUNTRY	
REPORT no.	

Date of report	

Place, date and time of Inspection	Name of cold store, date and time vaccines entered into cold store

PART I-ADVANCE NOTICE

MAIN DOCUMENTS	Date received by consignee	Copy airway bill (AWB)	Copy of packing list	Copy of Invoice	Copy of lot release certificate
Pre-advice					
Shipping notification		Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

List other documents (if requested)	

PART II- FLIGHT ARRIVAL DETAILS

AWB number	Airport of destination	Flight Number	ETA as per notification		Actual time of arrival	
			Date	Time	Date	Time

NAME OF CLEARING AGENT: _____ ON BEHALF OF: _____

PART III- DETAILS OF VACCINE SHIPMENT

Purchase order number	Consignee	Vaccine description (Type and doses/vial)	Manufacturer	Country

Vaccine				Diluent/droppers			
Lot number	Number of boxes	Number of vials	Expiry date	Lot number	Number of boxes	Number of units	Expiry date

(Continue on separate sheet if necessary)

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

No. = number

[1] WHO recommends that all UN agencies, countries and non-governmental organizations procuring vaccines adopt this report.

Report No.	

PART IV-DOCUMENTS ACCOMPANYING THE SHIPMENT

Invoice	Packing list	Lot release certificate	Vaccine arrival report	Other
Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	
Comments				

PART V- STATUS OF SHIPPING INDICATORS

Total number of boxes inspected			
Coolant type:	Dry ice ☐	Ice packs ☐	No coolant ☐
Temperature monitors present:	VVM ☐	Cold chain card ☐	Electronic device ☐

PROVIDE BELOW DETAILS OF STATUS ONLY WHEN PROBLEMS ARE OBSERVED:

Box number	Lot number	Alarm in electronic device		Vaccine vial monitor				Cold chain monitor				Date/time of inspection
		Yes	No	1	2	3	4	A	B	C	D	

(Continue on separate sheet if necessary)

PART VI- GENERAL CONDITIONS OF SHIPMENT

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

PART VII- NAME AND SIGNATURE

Authorized Inspection Supervisor DATE **Central Store or EPI Manager DATE**

For UNICEF Country Office use only

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

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Annex 2: Summary calculations in vaccine management

Calculation of annual vaccine needs for a health facility

	A	x	B	x	C	x	D	=	E
	Children aged 0–11 months (number)		Doses in the immunization schedule		Wastage factor		Coverage rate (%)		Total doses/ year
BCG	2700		1		2		95%		5140
OPV	2700		4		1.17		90%		11 370
DTP/HepB/ Hib	2700		3		1.17		90%		8530
Measles	2700		1		1.54		80%		3330
PCV	2700		3						
Rota	2700		2						

Calculation of quantity to be used during the supply period

	E	x	F	=	G
	Total doses required/ year		Duration of storage (3 months) (3/12)		Total doses required for a given period (quarter)
BCG	5140		0.25		1300
OPV	11 370		0.25		2850
DTP/HepB/ Hib	8530		0.25		2140
Measles	3330		0.25		830
PCV					
Rota					

Determination of minimum stock

	G	x	H	=	
	Total doses required for a given period (3 months)		Reserve stock (%)		Minimum or reserve stock (doses)
BCG	1300		25%		320
OPV	2850		25%		710
DTP/HepB/ Hib	2140		25%		540
Measles	830		25%		210
PCV					
Rota					

Determination of maximum stock

	G	+		=	L
	Total doses required for a given period (3 months)		Minimum or reserve stock (doses)		Maximum stock (doses)
BCG	1300		320		1620
OPV	2850		710		3560
DTP/HepB/ Hib	2140		540		2680
Measles	830		210		1040
PCV					
Rota					

Calculation of critical stock

	G	x	J	+		=	K
	Total doses required for a given period (3 months)		Order/storage period (1.5/3)		Minimum or reserve stock (doses)		Critical stock (doses)
BCG	1300		0,5		320		980
OPV	2850		0,5		710		2140
DTP/HepB/ Hib	2140		0,5		540		1610
Measles	830		0,5		210		630
PCV							
Rota							

Calculation of quantities to be ordered

	L	K	M
	Maximum stock (doses)	Quantity in stock (doses)	Stock to be ordered (doses)
BCG	1620	960	
OPV	3560	2420	
DTP/HepB/ Hib	2680	1810	
Measles	1040	510	
PCV			
Rota			

Annex 3: Selected commonly used temperature monitoring devices

Cold room temperature indicators

One data logger which is not WHO/PQS prequalified is currently available for monitoring cold room temperatures and generating GSM alarms. The available model is offered with an auto-dialer accessory that facilitates global system for mobile communication (GSM) alarm dial out. The accessory must be specified. Channel models 8, 12 and 16 are available and are appropriate for continuous monitoring of temperature in one, two or three cold rooms respectively, each of up to 40 m3 if they are situated within approximately 100 m of each other. This also allows provision for monitoring room temperature in cold room proximity and electrical supply from a national or local grid or generating set.

The data logger senses temperatures at user defined intervals and an aggregate of sensed temperatures is stored and transferred to a dedicated desktop computer mounted in the immediate proximity of the data logger which has two full-sized PCI ports available and is powered through an uninterruptable power supply to prevent data loss should power to the computer be interrupted during a data save cycle. The data logger has a built in battery backup. The data logger, which can be configured by the user, automatically generates reports of temperature excursions, and a graphical history of temperatures. Data are stored as a permanent record on the computer hard disk and can be communicated via USB modem or wi-fi to other locations for centralized monitoring. All cold rooms should be equipped with data loggers that monitor temperatures continuously and store data as a permanent record. Specific training is required for setting up, reporting and fault diagnosis of these data loggers. Installation by qualified technicians is required.

Fridge temperature monitors

An electronic temperature indicator is used to monitor the correct storage temperature of vaccines and other perishable goods in refrigerators. It shows if a product, such as vaccine, has been exposed to temperatures beyond assigned alarm settings described above. While 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 (in °C/°F); 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 is approximately two to three years (see PQS).

Freeze indicators

A freeze indicator is a digital monitor showing if the vaccine has been exposed to temperatures below 0°C for a certain time. Once an alarm is indicated, the device cannot be reset for reuse; it must be replaced. The monitor is designed for freeze-sensitive vaccines such as Penta/HepB/Hib liquid/PCV/Rota/TT/DT/Td vaccines. Freeze indicators monitor freeze-sensitive vaccines during storage and transport. They can be used continuously or many times over their shelf life (five years) if not exposed below 0°C for more than a 60-minute period. They change from "check" to "cross" when exposed below 0°C for more than a 60-minute period. When the indicator shows a "cross" they must be discarded.

To ensure end-to-end temperature monitoring, continuous monitoring of vaccine temperatures is required rather than occasional monitoring or twice daily spot checks. Thermometers are still used extensively to monitor temperature twice daily, but continuous monitoring devices will progressively replace these. No thermometers are prequalified except ones designed specifically for cold rooms.

Annex 4: Analysis and interpretation of vaccine wastage data with vaccination coverage

Refer to the monthly rows to see the monthly movements of districts from class A (high coverage/low vaccine wastage rates) to class D (low coverage/high vaccine wastage rates).

Assessment of districts by class performance (e.g. of monthy monitoring from Ghana)

DVD-MT Ghana — 2012

National

Districts	Monthly births	Vaccinations points	BCG Jan-12	BCG Feb-12	BCG Mar-12	BCG Apr-12	BCG May-12	BCG Jun-12	OPV Jan-12	OPV Feb-12	OPV Mar-12	OPV Apr-12	OPV May-12	OPV Jun-12	Penta Jan-12	Penta Feb-12	Penta Mar-12	Penta Apr-12	Penta May-12	Penta Nov-12	Penta Dec-12
Adansi North	517		clas_D	clas_D	clas_D	clas_D	clas_D		clas_C	clas_C	clas_C	clas_C	clas_C		clas_D	clas_D	clas_D	clas_D	clas_D		
Adansi South	503		clas_D	clas_C	clas_C	clas_D	clas_C		clas_C	clas_C	clas_C	clas_C	clas_C		clas_C	clas_D	clas_D	clas_D	clas_D		
Afigya-Kwabre	173		clas_A	clas_A	clas_A	clas_A	clas_A		clas_A	clas_A	clas_A	clas_A	clas_A		clas_A	clas_A	clas_A	clas_A	clas_A		
Ahafo-Ano North	331		clas_C	clas_C	clas_D	clas_D	clas_D		clas_C	clas_C	clas_C	clas_C	clas_C		clas_D	clas_D	clas_D	clas_D	clas_D		
Ahafo-Ano South	615		clas_B	clas_B	clas_B	clas_B	clas_B		clas_C	clas_C	clas_A	clas_A	clas_A		clas_C	clas_C	clas_A	clas_A	clas_A		
Amansie Central	300		clas_D	clas_D	clas_D	clas_D	clas_D		clas_D	clas_B	clas_D	clas_D	clas_D		clas_C	clas_A	clas_C	clas_C	clas_C		
Amansie West	500		clas_B	clas_D	clas_B	clas_B	clas_D		clas_C	clas_C	clas_A	clas_C	clas_A		clas_C	clas_D	clas_B	clas_D	clas_B		
Asante-Akim North	582		clas_A	clas_A	clas_A	clas_A	clas_A		clas_C	clas_C	clas_C	clas_C	clas_C		clas_C	clas_C	clas_C	clas_C	clas_C		
Asante-Akim South	446		clas_D	clas_D	clas_D	clas_D	clas_D		clas_C	clas_C	clas_C	clas_C	clas_C		clas_C	clas_C	clas_C	clas_C	clas_C		
Asante-Mampong	319		clas_A	clas_C	clas_C	clas_C	clas_C		clas_C	clas_D	clas_C	clas_C	clas_C		clas_C	clas_D	clas_D	clas_D	clas_D		
Atwima-Kwanwoma	247		clas_B	clas_B	clas_B	clas_B	clas_B		clas_A	clas_A	clas_A	clas_A	clas_A		clas_A	clas_A	clas_A	clas_A	clas_A		
Atwima-Mponua	419		clas_C	clas_C	clas_C	clas_C	clas_C		clas_A	clas_A	clas_A	clas_A	clas_A		clas_A	clas_A	clas_A	clas_A	clas_A		
Atwima-Nwabiagya	674		clas_B	clas_A	clas_A	clas_A	clas_A		clas_C	clas_A	clas_A	clas_A	clas_A		clas_D	clas_B	clas_B	clas_B	clas_B		
Bekwai	736		clas_D	clas_D	clas_D	clas_D	clas_D		clas_C	clas_C	clas_C	clas_D	clas_D		clas_C	clas_C	clas_C	clas_C	clas_D		
Bosome-Freho	189		clas_D	clas_D	clas_D	clas_D	clas_D		clas_C	clas_C	clas_C	clas_C	clas_C		clas_C	clas_C	clas_C	clas_D	clas_C		
Bosomtwe	236		clas_A	clas_A	clas_A	clas_A	clas_A		clas_A	clas_A	clas_A	clas_A	clas_A		clas_A	clas_A	clas_A	clas_A	clas_A		

Interpretations:

- **class A:** high coverage & low wastage → **Congratulate & Keep up!**
- **class B:** high coverage & high wastage → Encourage for better planning & MDVP
- **class C:** low coverage & low wastage → Encourage to overcome wastage fear
- **class D:** low coverage & high wastage → **Urgent support needed!**

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