Introducing Pneumococcal Conjugate Vaccine In Ethiopia

Training Manual for Health Workers

June 2011

Table of Contents

PREFACE

This training manual has been developed primarily for EPI managers and health workers involved in immunization services delivery to prepare them for the introduction of the 10-valent Pneumococcal Conjugate Vaccine (PCV) that will be introduced into the national infant immunization schedule from September 2011.

The training manual was adapted from the WHO introduction handbook for PCV and also incorporates product information from the current manufacturer of PCV 10 – GlaxoSmithKline. As such, all references made to PCV are in effect, references to Synflorix™, a liquid formulation without preservative presented in a two-dose vial.

Although this training manual is being released with the introductory process for the PCV, it will continue to be a useful reference guide long afterwards for new health workers being inducted into immunization services delivery.

An abridged version of this training manual has been developed for health extension workers and translated into four local languages for ease of reference. A training video has also been developed to complement the training manual and users of the training guide are encouraged to view the video as well.

The manual was developed by the national technical Subcommittees designated to spearhead the introduction of the PCV, led by the Training Subcommittee. It is a product of the team effort of technical staff of the Federal Ministry of Health and dedicated officers from various partner agencies.

It is the hope of the Federal Ministry of Health that the manual will contribute to a smooth introduction of pneumococcal vaccine and improve immunization service delivery for all infants in Ethiopia.

ACKNOWLEDGEMENT

The Federal Ministry of Health extends its sincere appreciation to all persons, agencies and organizations that were involved in the production of this training manual and the training video.

The following agencies and organizations are specifically acknowledged:

- *The World Health Organization*
- *The United Nations Children's Fund*
- *Clinton Health Access Initiative*
- *Network for Education and Support in Immunization – University of Antwerp, Belgium*
- *The Ethiopian Pediatric Association*
- *CORE GROUP Ethiopia*
- *John Snow Inc./L-10K*
- *GlaxoSmithKline*

Though not possible to list all who participated in the preparation of the training manual individually, the Federal Ministry of Health sincerely appreciates all contributions made in the development of this manual.

FOREWORD

The Federal Ministry of Health will be introducing a new vaccine into the routine infant immunization schedule nationwide with effect from September 2011. The new vaccine is the 10-valent pneumococcal conjugate vaccine (PCV) and will be administered at the same time with the existing DPT-HepB-Hib (pentavalent) vaccine at 6, 10 and 14 weeks of age.

The 10-valent pneumococcal conjugate vaccine will protect against the most severe forms of pneumococcal disease in childhood such as meningitis, pneumonia and bacteremia. The 10 serotypes (valencies) contained in the PCV cause approximately 80% of the pneumococcal disease burden in the country and it is therefore expected that an equivalent reduction in the disease burden due to pneumococcal diseases will be achieved with the vaccine once introduced. The primary objective of introducing PCV into the routine infant immunization program is to reduce the morbidity and mortality due to *streptococcal pneumoniae* infections, which are the leading cause of pneumonia in Ethiopia. Pneumonia accounts for significant morbidity and up to 28% of all deaths among children under 5 years.

This training manual is intended to equip health managers and service providers at all levels with sufficient information for smooth integration of the new pneumococcal vaccine into the routine infant immunization schedule.

PCV has some unique characteristics that necessitate special attention by health workers. First, the presentation of PCV to be provided by the Federal Ministry of Health is a ***preservative-free liquid injectable formulation presented in two-dose vials***. Due to the lack of preservative, health workers have to be especially careful not to return opened vials back to the refrigerator as they do with other liquid vaccines such as polio and tetanus vaccines. ***Both doses in each PCV vial must be used within six hours of opening the vial and all unused doses must be discarded six hours after opening the vial or at the end of the vaccinating session – whichever comes first.*** Secondly, since PCV and the pentavalent vaccine (DPT-HepB-Hib) will be administered at the same time (visit) with separate AD syringes, each vaccine has been assigned a specific site (thigh) and order of administration. During vaccination sessions the pentavalent vaccine will first be injected into the left upper outer thigh of the infant followed by the PCV which will be injected into the right upper outer thigh of the infant.

This training manual will first be used during the training sessions for the introduction of the PCV vaccine but will also subsequently serve as a reference guide for all health workers and managers involved in providing immunization services. It contains general information on best practices of managing immunization services and specific information for the handling of PCV. It is my sincere hope that the PCV will be introduced successfully and sustained smoothly for the benefit of Ethiopian children.

The Federal Ministry of Health is committed to the prevention and control of vaccine preventable diseases in the country. We believe that the concerted efforts of all stakeholders involved in the introduction of PCV in Ethiopia will contribute to the achievement of the Millennium Development Goals (MDG 4). We hope that this handbook will also significantly contribute to improve the skills of health workers, to achieve the targets set in the Health Sector Development Plan (HSDP IV).

H.E Dr Kesetebirhan Admasu (MD, MPH)
State Minster of Health

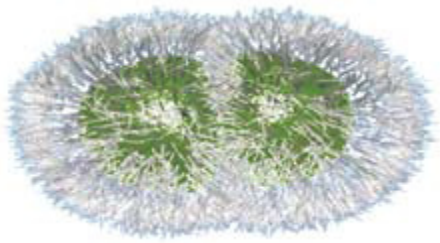
ACRONYMS AND ABBREVIATIONS

AD	Auto Disable Syringes
AEFI	Adverse Events Following Immunization
BCG	Bacilli de Calmette Guerin (Vaccine against Tuberculosis)
CHAI	Clinton Health Access Initiative
CSF	Cerebro Spinal Fluid
DPT	Diphtheria, Pertusis, Tetanus
EPI	Expanded Programme on Immunization
GSK	GlaxoSmithKline
HepB	Hepatitis B
Hib	*Haemophilus influenzae* type b
HIV	Human Immunodeficiency Virus
IMNCI	Integrated Management of Neonatal and Childhood Illnesses
MCH	Maternal and Child Health
OPV	Oral Polio Vaccine
PCV	Pneumococcal Conjugate Vaccine
PCV 10	Pneumococcal Conjugate Vaccine 10
S. pneumo	*Streptococcus pneumoniae*
TT	Tetanus Toxoid
UNICEF	United Nations Children's Fund
VVM	Vaccine Vial Monitor
WHO	World Health Organization

1 Pneumococcus and Pneumococcal Vaccine

1.1 Pneumococcus and Pneumococcal Disease

Pneumococcus (also known as *Streptococcus pneumoniae*) is a bacterium that causes a group of diseases called Pneumococcal disease. These include severe diseases such as pneumonia, meningitis, bacteraemia, and milder diseases such as middle ear infection (otitis media), sinusitis and bronchitis. Pneumococcus is classified into serotypes, denoted by numbers and letters (e.g. 18C, 23F). There are over 90 known serotypes and the prevalence of different serotypes varies by regions of the world. Different serotypes also have differing potential to cause different diseases (e.g. meningitis, pneumonia) in various age groups. Some strains also have greater potential for antibiotic resistance. Pneumococcus is a normal resident of the human nasopharynx. The 13 most common serotypes of pneumococcus cause 80% to 93% of serious pneumococcal diseases in children.



Normal resident of human nasopharynx

> 90 serotypes based on their polysaccharide capsule

13 serogroups account for most (>80%) serious pneumococcal disease in children worldwide

Streptococcus pneumoniae

According to the World Health Organization (WHO) and United Nations Children's Fund (UNICEF) Global Action Plan for the Prevention and Control of Pneumonia (GAPP), pneumonia kills more children than any other illness in the world. Given the high burden of under-five mortality associated with pneumonia, pneumonia control efforts are critical to achieving the Millennium Development Goal 4 (MDG4). WHO estimates that over 800,000 children under 5 years of age die from pneumococcal disease each year with those less than 2 years of age, especially in developing countries, being most at risk[1]. In Ethiopia, an estimated 1 in every 4 deaths among children under-five years of age, is caused by pneumonia every year.

1.2 Transmission

Pneumococcus is transmitted through the following ways:

- Droplet spread or contact with surfaces contaminated with the secretions. Any time a patient or a healthy carrier coughs or sneezes, she/he releases droplets into the air. This fluid can contain the Pneumococcus bacteria. Another individual may walk by and inhale the bacteria without even knowing it and the bacteria can settle in their nose.

[1] WHO Estimates 2009

- Direct Contact with respiratory secretions from patients or healthy carriers, who may carry pneumococci in their nose or throat and transmit it on fingers, cloths (handkerchiefs) and objects (e.g. cups). Pneumococcus may then spread from the nose and throat to the blood stream causing bacteraemia (presence of bacteria in the blood) and then infect distant sites such as the meninges (lining of the brain) causing meningitis. It can also move to the lung causing pneumonia, or can spread to adjoining sites causing otitis media (ear infections) or sinusitis (sinus infections).

1.3 Pneumococcal Diseases

Pneumococcus causes both severe and less severe diseases. The most common severe form of pneumococcal disease is pneumonia. Less commonly, pneumococcus causes invasive pneumococcal diseases such as meningitis and blood stream infections (sepsis). Meningitis can be fatal or leave survivors with permanent disabilities. Less severe infections include ear infections (otitis media), sinus infections (sinusitis) and bronchitis.

1.4 Epidemiology

Children under 5 years of age (especially those under two years of age) and the elderly are most at risk of developing and dying from pneumococcal disease. In Ethiopia, over 100,000 children become ill with pneumococcal disease each year. Pneumonia accounts for approximately 28% of all deaths among children under 5 years of age. Case fatality rates may be up to 18% for pneumonia and as high as 83% for meningitis[2]. Apart from young age and the elderly, other risk factors for pneumonia include HIV infection, influenza virus infection, overcrowding, indoor air pollution and for infants, lack of breast-feeding and incomplete immunization (e.g. measles, *Haemophilus influenza* type b[Hib] and pertussis).

1.5 Diagnosis

It is difficult to diagnose pneumococcal disease, particularly pneumococcal pneumonia. Pneumococcal pneumonia is hard to diagnose because it presents like common cold, flu or malaria. In fact, pneumococcus often goes undetected. People may not realize that it is a serious disease until it lasts longer than other mild conditions that mimic it. While a health worker can diagnose pneumonia using Integrated Management of Neonatal and Childhood Illnesses (IMCNI) guidelines, the diagnosis of pneumococcal pneumonia requires laboratory testing. A health worker will diagnose pneumococcal pneumonia based on the medical history, physical examination, blood culture (for bacteraemia in a small number of pneumonias) and/or a chest x-ray. Pneumococcal meningitis is normally diagnosed by performing a lumbar puncture, which involves inserting a needle into the spine through the lower back to obtain a sample of cerebrospinal fluid (CSF) for culture and microscopy. Otitis media and sinusitis are normally diagnosed based on medical history, clinical examination and bacteriological testing of pus from the middle ear and nasopharyngeal secretions respectively. However, pneumococcus is a difficult bacterium to detect and frequently goes undetected even when blood or CSF samples are available. Serotyping of pneumococcus is only possible if the bacterium is cultured and even then it is only conducted in certain specialized laboratories.

1.6 Protection, Prevention and Treatment

[2] http://pneumodel.simpal.com/_/PneuModel.html

1.6.1 Vaccination

Safe and effective vaccines now exist to protect against many (but not all) strains of pneumococcal disease. Vaccines are the most cost- effective way for preventing pneumococcal diseases.

Pneumococcal diseases will occur less frequently in immunized children. However, in order to maximize protection of children, additional disease control measures should be reinforced such as hand washing, nutrition and breast feeding.

1.6.2 Hand washing

Addressing environmental factors such as indoor pollution and encouraging good hygiene like regular hand washing contribute to reducing the number of children who fall ill with pneumonia. While improvement of living conditions (reduced crowding and indoor air pollution) and nutrition can reduce the risk of pneumococcal disease and death, they are not as effective as vaccines in preventing pneumococcal disease.

1.6.3 Adequate Nutrition

Under-nutrition may place children at an increased risk of developing pneumonia in two ways: First, malnutrition weakens a child's overall immune system, as an adequate amount of protein and energy is needed for proper immune system functioning. Secondly, undernourished children have weakened respiratory muscles, which inhibit them from adequately clearing secretions found in their respiratory tracts.

1.6.4 Exclusive Breast Feeding

It is widely recognized that children who are exclusively breastfed develop fewer infections and have less severe illnesses than those who are not. Breast milk contains the nutrients and antibodies needed by the child to survive and develop, and specifically for a child's immune system to function properly. Infants under six months old who are not breastfed are five times more at risk of dying from pneumonia as infants who are exclusively breastfed for the first six months of life. Furthermore, infants 6 - 11 months old who are not breastfed are also at an increased risk of dying from pneumonia compared to those who are breastfed.

1.6.5 Zinc Supplementation

Children who lack sufficient amounts of specific micronutrients, particularly zinc, face additional risks of developing and dying from pneumonia. Zinc intake helps reduce the incidence of pneumonia and the severity of the disease.

1.6.6 Treatment

Pneumococcal disease, being bacterial, can be treated with antibiotics especially penicillins (e.g. amoxicillin) or co-trimoxazole. Penicillins are commonly used to treat pneumococcal infections. Erythromycin can be used as an alternative in those who are allergic to penicillins. For very severe pneumonia, penicillin is used in combination with gentamicin or cholaramphenicol. Treatment should follow the national guidelines. However, in many countries including Ethiopia, strains of pneumococcus are becoming resistant to these antibiotics.

In Ethiopia about 30% of all under 5 years with pneumonia do not access appropriate health care. Vaccinating against pneumococcal disease is therefore the most cost-effective way to prevent substantial mortality and morbidity in the underserved populations of the poorer parts of the country.

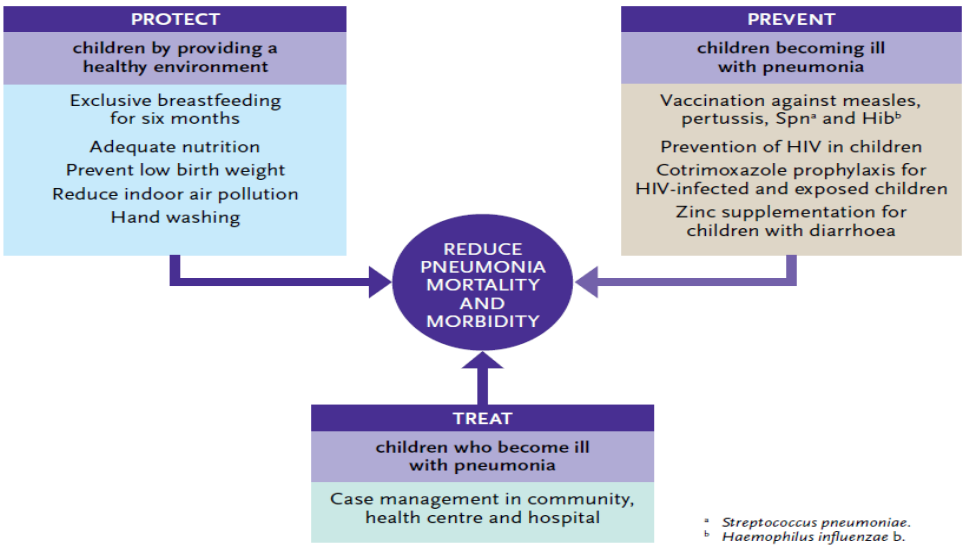


Figure 1: Global Action for the Prevention of Pneumonia

1.7 Pneumococcal Conjugate Vaccine

1.7.1 Nature of the vaccine:

Pneumococcal vaccines protect against severe forms of pneumococcal disease, such as meningitis, pneumonia and bacteraemia. The vaccine will not protect against these conditions if they are caused by other agents other than pneumococcus or other strains of pneumococcus that are not contained in the vaccine.

The vaccine that will be introduced in Ethiopia in 2011 is called Synflorix™. It is a safe and effective vaccine that protects against 10 common serotypes that cause pneumococcal diseases and is therefore referred to as PCV10. PCV10 is a liquid vaccine that is provided in a 2-dose vial. It has no preservative and is therefore the only liquid vaccine without preservative in our country. The vaccine is sensitive to heat and freezing and must be handled appropriately (see Chapter 2). In Ethiopia, the introduction of PCV will avert an estimated 35,000 deaths in a single birth cohort over a five year period.

Figure 2: Synflorix. The vaccine is packaged in a 2-dose vial and is in liquid form

PCV10 comes in a two-dose vial and does not contain a preservative. All opened vials of Synflorix must be discarded 6 hours from first opening or at the end of each session, whichever comes first. Open vials of PCV should not be returned to the refrigerator.

1.7.2 PCV Administration

PCV will be administered intramuscularly on right upper outer thigh at a dose of 0.5 ml, according to the vaccination schedule, at 6, 10 and 14 weeks. PCV and pentavalent (DPT-HepB-Hib) vaccines will be given at the same visit. However, pentavalent vaccine should be given first in the left upper outer thigh.

- Shake the vaccine vial gently to obtain a uniform solution. Observe the vial content for unusual appearance and particles. If either is observed, the vial must be discarded.
- Draw 0.5ml of PCV from the vial using the 0.5ml AD syringe.
- Instruct the mother on how to hold the baby for vaccine administration.
- Clean the right upper outer thigh with a swab and administer the vaccine intramuscularly. Press the injection site firmly for a few seconds. Do not massage.
- Dispose the used needle and syringe immediately into the safety box and do not recap the needle.
- If a vial is opened for 1 child and another child is not immediately available to be vaccinated with the remaining dose in the vial, then write the time that the vial was opened on the vial and place the vial back in the vaccine carrier's foam pad and away from any potential contamination.
  Discard the vial 6 hours after opening or the end of the vaccination session, whichever comes first.

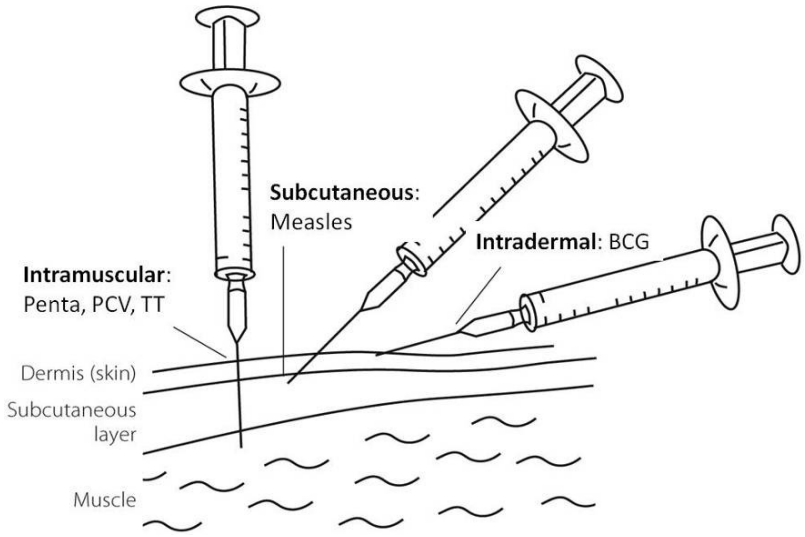


Figure 3: Different needle positions for various vaccines

PCV 10 comes in a two-dose vial and contains no preservative.

- ***Write the time vial was opened on the vial label***
- ***Place vaccine vial in vaccine carrier's foam pad (never back in the refrigerator)***
- ***If any dose is unused, at the end of vaccination session or after 6 hours, the vial must be discarded whichever comes first.***

1.7.3 Vaccination Schedule

All infants 6 weeks to 11 months of age are eligible for vaccination with PCV

The FMOH of Ethiopia recommends that infants be given three doses of PCV at *6, 10* and *14 weeks of age*.

If children do not get a second or third dose of PCV on time, do not restart: they should continue with the remaining doses only. Children should receive all the three doses of PCV and other vaccines by their first birthday; however, if a child receives their first dose of PCV at 11 months of age, they should complete the remaining two doses with the interval of 4 weeks of time between doses. The following table shows over all vaccination schedules of children below 1 year of age in Ethiopia.

Table 1. Routine immunization schedule, Ethiopia

Vaccine	Age

	Birth	6 weeks	10 weeks	14 weeks	9 months
BCG	X				
Oral polio Vaccine (OPV)	X	X	X	X	
DPT-HepB-Hib (Pentavalent)		X	X	X	
Pneumococcal Conjugate Vaccine (PCV)		X	X	X	
Measles					X

PCV vaccination should be integrated with pentavalent vaccine (DPT-HepB-Hib) as indicated in Table 2.

Table 2. Vaccination schedule for children who have started pentavalent vaccine without concurrent PCV doses

Vaccination status if infant aged less than 1 year at the time of vaccine introduction	Vaccine/s to be administered at first contact	Subsequent contact – after four weeks	Subsequent contact – after four more weeks
Never received any Penta	*Penta 1 & PCV 1*	*Penta 2 & PCV 2*	*Penta 3 & PCV 3*
Already received Penta 1	*Penta 2 & PCV 1*	*Penta 3 & PCV 2*	*PCV 3*
Already received Penta 2	*Penta 3 & PCV 1*	*PCV 2*	*PCV 3*
Already received Penta 3	*PCV 1*	*PCV 2*	*PCV 3*

Exercise

A. **Short questions**

1. What will be the vaccination schedule for administration of pneumococcal vaccine in Ethiopia?
2. What should be done for under one year age child who comes to a session late for the recommended age of vaccination for PCV?

B. **Multiple Choice/ True or False Questions**

Q1: The first dose of Pneumococcal vaccine is given at:

a. 9 months of age along with measles vaccine
b. at the same time as Pentavalent (DTP-HepB-Hib) vaccine
c. anytime before two years

Q2: A child comes to a vaccination session at 10 weeks of age for a second dose of pentavalent vaccine and he has never received Pneumococcal vaccine. This child cannot be given the first dose of Pneumococcal vaccine. **True/ False**

Q3: Which vaccines, if any, are each of the following children due to receive?

- A new born
- A ten months old child who has had BCG, OPV3, DPT-HepB-Hib3
- An eight months old child who has had BCG, OPV3, DPT-HepB-Hib3, PCV10-3
- A six weeks old child who has had BCG and OPV-0
- A five weeks child who has never been immunized
- An 11 months old child who has never been immunized

Q4: How many doses are in one vial of Pneumococcal vaccine (PCV 10) to be introduced in Ethiopia?

a. one dose
b. two doses
c. five doses
d. ten doses

Q5: Pneumococcal conjugate vaccine to be introduced in Ethiopia is:

a. fully liquid vaccine with preservative
b. fully liquid vaccine without preservative
c. lyophilized vaccine and will be mixed with diluent

Q6: Pneumococcal vaccine is administered as a 0.5 ml dose by intramuscular injection. **True/ False**

Q7: Pneumococcal vaccination injection should be given:

a. Right upper thigh
b. Left upper thigh
c. Same site as pentavalent vaccine injection
d. Site opposite to where pentavalent injection is given
e. a and d

Q8: Unused opened vials of pneumococcal vaccine can be kept for use in later sessions. **True/ False**

Q9: Pneumococcal vaccine should not be given to a child with high fever (temperature ≥39°C); wait until the condition improves. **True/ False**

2 Cold Chain and Vaccine Management

2.1 The Cold Chain

Vaccines are sensitive to heat and freezing and must be kept and transported at the correct temperature from the time they are manufactured until they are administered. The system used for keeping and distributing vaccines in good condition is called the cold chain. The cold chain consists of a series of storage and transport links, which are designed to keep vaccines within an acceptable temperature range until it reaches the end user.

2.2. Estimation of Vaccine Requirements

The availability of adequate and quality vaccine is critical to immunization services. Effec-tive management and storage of supplies can help save on programme costs, prevent high wastage rates and stock-outs, and improve the safety of immuniza-tions.

Estimating vaccine and injection equipment needs for PCV should be based on the number of children to be vaccinated, target coverage and wastage factor (1.1 for PCV). All levels should always have 25% buffer stock. In the first year of introduction, children below one year of age already vaccinated with pentavalent vaccine will be eligible for pneumococcal vaccine and the requirement may double than the pentavalent vaccine target for that year, therefore, this should be taken into account in the forecast for PCV10. The most common method for estimation of vaccine requirements is based on target population.

2.2.1 Estimating vaccine needs on the basis of target population

To estimate vaccines needs on the basis of target population, basic parameters such as target population (the number of children within the targeted age), planned annual immunization coverage, immunization schedule and wastage rate are necessary.

Annual need of vaccines = Target Population x Number of doses x Desired immunization coverage x Wastage factor

2.2.2. Estimating required net volume for vaccines storage

A short-cut method based on vaccine volume per fully immunized child (FIC), is usually used when introducing new vaccines.

The total storage net volume is obtained by multiplying the volume per fully immunized child and the total number of expected children during the course of the year (this will depend on the objectives of immunization coverage).

Table 3: Calculation of vaccine storage volume per fully immunized child (including two doses of TT for pregnant women)

Vaccines	No. of doses per vial	No. of doses for immunization	Packed volume per dose (cm^3)	Wastage		Storage volume cm^3 = B*C*E	Storage volume (liters) = B*C*E
				W/Rate	W/Factor =100/100-D		
	A	B	C	D	E	F	
Oral polio	10	4	2	10	1.11	8.88	0.00888
Measles	10	1	2.5	40	1.60	4.00	0.004
Measles diluents*						4.00	0.004
BCG	20	1	1.0	50	2.00	2.00	0.002
BCG diluents *						2.00	0.002
DTP-Hep B-Hib	1	3	12.86	10	1.05	40.51	0.04051
PCV	2	3	4.80	10	1.11	15.98	0.01598
TT	10	2	3	10	1.11	6.66	0.00666
Net storage volume per fully immunized child (cm^3)						84.03 cm^3	0.08403L
*For woreda and above cold stores Storage volume of Diluents will be deducted							

Required Storage Volume in liters = Net volume per fully immunized child (in lit.) X Number of children under 11 months X Immunization coverage target

The next step is to determine the necessary cold chain capacity to accommodate the vaccine volume we have just calculated. Now we need a multiplying factor or volume factor which is 1.2 to 2.0 for refrigerators or freezers that takes into consideration the need for air circulation between vaccine boxes. The result of this calculation gives an overall capacity needed for the cold chain.

Required Storage Capacity = Vaccines Storage Volume X Equipment Volume Factor

Example

If the total population and target (under one year old children) population of a facility is 50000 and 3.5% respectively and planned coverage is 90%, what is required cold chain capacity?

- Target population: 50,000 * 3.5/100 = 1, 750 children
- Children to be vaccinated: 1750 * 90/100 = 1,575 children
- Vaccine storage volume: 1575 * 0.08403 = 132.35 liters
- Equipment volume factor of refrigerators and freezers: 2
- Required capacity for annual supply: 132.35 lit * 2 = 264.69 liters
- Required capacity for supply period (one month): 264.69/12 = 22.06 liters

Therefore for the above health facility one RCW50 KE refrigerator will be sufficient.

2.3 Selecting Cold Chain Equipment

Once the capacity needs for refrigeration have been determined, the officer in charge can select or request the right model of refrigerators.

Table 4: Common cold chain equipment in Ethiopia that meet WHO/UNICEF standards

NO	Model	Manufacturer	Vaccine storage capacity (Lit)	Remarks	NO	Model	Manufacturer	Vaccine storage capacity (Lit)	Remarks
1	PR 265 EK	Zero	37.5	Refrigerator	11	MF 314	Vestfrost	264	Freezer
2	Sun Frost	Solar	38.7	Solar	12	MK 204	Vestfrost	75	Refrigerator
3	TCW 1152	Dometic	169	Refrigerator	13	MK 144	Vestfrost	45	Refrigerator
4	TCW 1990	Dometic	37.5	Refrigerator	14	MK304	Vestfrost	105	Refrigerator
5	VC-150 F	Dulas	85	Solar	15	V 110 EK	Sibir	17	Refrigerator
6	VC-65 F	Dulas	37.5	Solar	16	RCW 42 EK	Dometic	18.2	Refrigerator
7	VR50F	BP Solar	17.5	Solar	17	V 170 EK	Sibir	55	Refrigerator
8	MF 114	Vestfrost	72	Freezer	18	RCW 50 EK	Dometic	24	Refrigerator
9	PR 245 EK	Zero	18	Refrigerator	19	TCW 3000	Dometic	126	Refrigerator
10	MF 214	Vestfrost	192	Freezer	20				
11	V240KE	Sibir	55	Refrigerator					

2.4 Storage of Vaccines

It is very essential to store vaccines at every stage of the cold chain properly. The quantity of the vaccines required should be calculated for the period as mentioned.

While storing the vaccine, the following should be noted:

- Keep the packets containing the vaccines in a neat row;
- Similar vaccines should be stored in the same area, different vaccines should be kept separately to facilitate easy identification;
- Keep about 2 cm space between rows for circulation of air;
- The period of time in which any vaccine remains in cold chain stores without being used should be recorded,
- In chest type (top opening) refrigerators, store diluents and freeze sensitive/early expiry date vaccines on the top and heat sensitive/late expiry date vaccines on the bottom. In vertical (front opening) refrigerators freeze sensitive vaccines and diluents must be kept on the lower shelves.

The suggested maximum length of storage at health-facility level is 1 month. Also keep in mind that the VVM status and expiry dates of vaccines must be monitored and must be used accordingly.

Each vial shows an expiry date. Never use vaccines when the expiry date has passed, even if the VVM shows no heat damage. In general, always apply the earliest-expiry-first-out (EEFO) principle.

Keep separate (date-wise) records of vaccine receipts, distribution and balance sheet for each type of vaccine and each size of vial.

PCV10 should be stored and transported between +2 to +8 ° Celsius at all levels. Do not freeze or place PCV10 vaccine on a frozen icepack. PCV10 vaccine loses potency and provides no protection if frozen. If there is doubt, the “shake test” can be performed to check whether the vaccine has been frozen (Refer to Section 2.5).

2.5 Preparing the vaccine

PCV10 should be administered as soon as possible after being removed from the refrigerator.

During an immunization session, vials are protected from heat for a longer period of time if they are inserted in a foam pad as shown in Figure 3.

Figure 3: Foam pad in use

In a fixed immunization session you need to complete certain tasks explained below

Condition the ice-packs *(Before the infants come for the immunization session)* by allowing ice-packs to stay at room temperature until ice begins to melt and water starts to form. This can take several hours at an ambient temperature of +20° Celsius and less time at higher temperatures. Check to see if an ice-pack has been conditioned by shaking it and listening for water. This will prevent the freeze-sensitive PCV from freezing. Use of chilled water packs is more preferable than conditioning frozen ice packs. Water packs can be chilled by keeping them in a cooling compartment for at least 24 hours at a temperature of 2-8° C.

- Prepare the vaccine carrier with conditioned ice packs or chilled water packs *(Before the infants come for the immunization)*
- Take the vaccine out of the fridge *(as soon as infants come for immunization)*
- Check the VVM and expiry date for validity.
- Inspect if the vaccine is frozen.
    - A fine white deposit with a clear colorless supernatant may be observed upon storage of the vial. This does not constitute a sign of deterioration.
- The vaccine should be well shaken before use.

2.6 Stock Management

Wherever vaccines are stored, a system of stock management must be in place to record vaccines received, and vaccines dispatched or used. This en sure that vaccines are used before their expiry date,

that the status of VVM is recorded at receipt and issue, and that there are no stock-outs or over-stocking.

In using vaccine control ledger/ stock card take into account that different batches of vaccine and supplies will be received on a regular basis and dispatched to the network of health facilities, or issued to health workers for immunization sessions.

It is important to distinguish between different batches of vaccine because they may have different expiry dates and should be used accordingly. Also, in the rare situation that there is a serious adverse event, it will be useful to know the exact description of the vaccine (manufacturer, batch number etc).

2.7 Cold Chain Monitoring Tools

Vaccines loose their potency due to either exposure to excessive heat or cold (pentavalent, PCV10 and TT) and light (BCG and measles).

The physical appearance of the vaccine may remain unchanged even after it is damaged which is permanent.

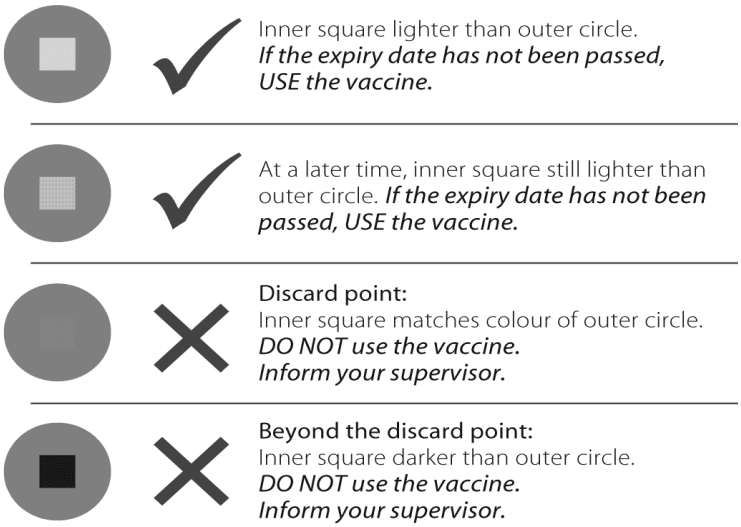
Evidence suggests that excessive cold or freezing could occur at any level and the vaccine handlers should take precautionary steps to prevent vaccine freezing and discard vaccines that are damaged due to freezing. To have potent vaccine in the cold chain system the officer in charge of vaccine management should use of VVM (Vaccine Vial Monitor), freeze indicators (freeze tag) and monitoring the use and wastage of vaccines

2.7.1 Vaccine Vial Monitor

Besides freezing, exposure to heat can also reduce a vaccine's potency. Therefore, protect the vaccine from exposure to heat >8°C

PCV-10 has a Vaccine Vial Monitor (VVM) on the vial cap. A VVM is a heat-sensitive label attached on the side of a vaccine vial for pentavalent, TT and OPV or, placed on the vial cap for PCV and measles. The white square inside the gray circle changes color (darkens) irreversibly when exposed to heat over period of time. By comparing the color of the inner square to that of the outer circle, users can determine the extent to which the vaccine has been exposed to heat and can decide whether to use the vaccine or not. Using the appearance of the white square of the VVM, a vaccine can be in any of the four stages indicated below. Vaccines in stage II should be used first since they are almost reaching the discard point. Only vaccine in stages I and II should be used. Vaccines that have reached stages III and IV should never be used but should be discarded.

How to read a Vaccine Vial Monitor (VVM)



2.7.2 Freeze-tag

A freeze indicator is an irreversible temperature indicator which shows if a product, such as vaccine, has been exposed to freezing temperatures.

It consists of an electronic temperature measuring circuit with associated LCD-display. If the indicator is exposed to a temperature below 0°C ± 0.3°C for more than 60 minutes ± 3 minutes the display will change from the "Tick" status into the "Cross" status as indicated on the picture below. The indicator is used to warn of freezing and is packed with DTP-HepB-Hib, TT and PCV vaccines. Shelf life is 5 years.

Figure 4: Freeze Tag

Not Activated
(Vaccine is ok)

Activated (Do shake test for freeze sensitive vaccines)

2.7.3 Shake Test

The "Shake test" can help give an idea whether adsorbed vaccines (DTP-HepB-Hib, PCV and TT) have been subjected to freezing temperatures likely to have damaged them. After freezing, the vaccine no longer has the appearance of a homogenous cloudy liquid, but tends to form flakes which settle at the bottom of the vial after shaking.

Sedimentation is faster in a vial which has been frozen than in a vial from the same manufacturer, which has not been frozen.

The test should be conducted for all boxes where freeze indicators are found to be activated or temperature recordings show negative temperatures.

Procedure:

Step1 — *Prepare a frozen control sample:* Take a vial of vaccine of the same type and batch number as the vaccine you want to test, and from the same manufacturer. Freeze solid this vial at (-) 20oC overnight, 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.

Step 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*.

Step 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.

Step 4 — *Allow to rest:* Leave both vials to rest by placing the vials on a table and not moving them further.

Step 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, the vial has probably been damaged by freezing and should not be used. Notify your supervisor.

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

If the shake test procedure indicates that the test sample has been damaged by freezing, you should notify your supervisor immediately. Identify and separate all vaccines that may have been frozen and ensure that none are distributed or used.

Note: Frozen samples can be used for shake tests only when testing the same vaccine from the same manufacturer and the same lot number. A new sample is needed for each manufacturer and lot number.

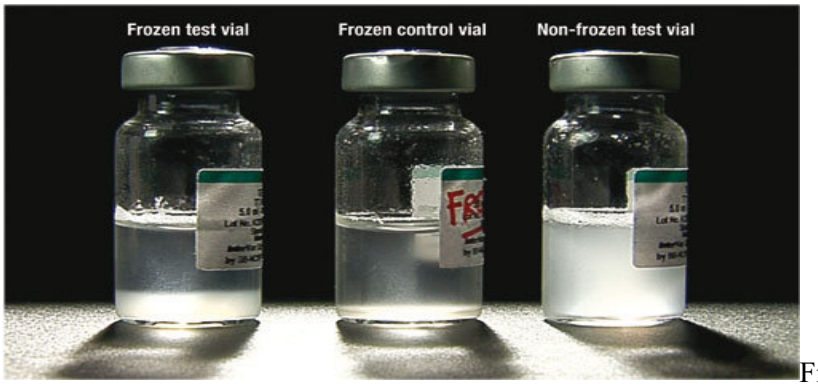


Figure 5: Shake test

2.8 Vaccine Wastage

Some degree of vaccine wastage is expected in any immunization service. Wastage can occur at any stage. It can occur in the cold store at central level, at various intermediate levels, at the point of use at an immunization session and during transportation. Reducing wastage depends upon better management at all levels. The factors associated with vaccine wastage can be classified as unavoidable and avoidable.

1. Unavoidable vaccine wastage factors

The most important unavoidable wastage factors include:

- The use of reconstituted and PCV vaccines that have to be discarded at the end of the session or **6 hours after drawing the first dose.**
- Other vaccines used in situations under which conditions for the multi-dose vial policy cannot be met.

2. Avoidable vaccine wastage factors

The following are some factors that can be controlled by improving vaccine management:

- Poor stock management resulting in over-supply and vaccines reaching expiry before use
- Cold chain failure that exposes vaccines to unacceptably high or low extremes of temperature. Incorrect dosage, e.g. the administration of three drops of OPV instead of two, or the injection of 0.6 ml of vaccine instead of 0.5 ml.
- Failure to comply with the multi-dose vial policy. Vials lost, broken or stolen.

2.9 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.

Initially, any vial opened during an immunization session should be thrown away after the session, irrespective of the type of vaccine and the number of doses remaining.

To ensure the optimal use of vaccines, WHO and UNICEF have issued directives authorizing the re-use, "under certain conditions", of opened multi-dose vials of liquid polio, TT and Hep B vaccines. Vaccines such as PCV, BCG and measles, are not included in these directives.

According to WHO's revised MDVP, OPV and TT (for Ethiopia) vaccines may be preserved and used for immunization up to 4 weeks on condition that they:

- have not expired
- have not been contaminated (aseptic rules observed when removing doses)
- have not been exposed to excessive cold or heat
- have not been immersed in water
- have not been disturbed or precipitated
- VVM has not reached to discard point (if existing)

2.10 Safe Waste Management

Sharps waste poses a serious health and environmental problem. Unsafe disposal can spread some of the very same diseases that we are trying to prevent. Leaving used syringes and needles in the open or on the ground puts the community at risk. Most frequently, children are the unfortunate victims of needle-stick injuries from haphazard disposal of needles and health workers from mishandling of equipment.

All used injection equipment (syringes and needles) should be discarded in a safety box immediately after use. These safety boxes should be leak-proof and tamper-proof and needles cannot easily pierce them.

Safety first!
DO NOT throw filled safety boxes in unprotected open areas.
Fill safety boxes only three-quarters full.
burn and bury.

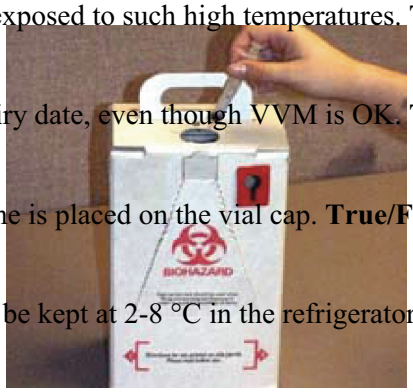


Figure 6: Safe disposal of sharps

Exercise

Q1: At the end of a session, a health worker has one open vial of pneumococcal vaccine with one dose remaining and two unopened vials of pneumococcal vaccine. Circle the correct action:

a) Keep all vials (opened and unopened) in the freezer

b) Discard all vials (opened and unopened)

c) Keep unopened vials back in refrigerator and discard opened vial of pneumococcal vaccine.

Q2: Since the liquid pneumococcal vaccine does not contain a preservative, it is unsafe to use open vials in subsequent sessions. **True/False**

Q3: The vaccine vial monitor (VVM) on the vaccine vial tells about whether the vaccine has been frozen in the past. **True/False**

Q4: The VVM on the vaccine vial shows whether the vaccine has been exposed to high temperatures and the duration for which it has been exposed to such high temperatures. **True/False**

Q5: A vaccine may be beyond expiry date, even though VVM is OK. **True/False**

Q6: VVM on Pneumococcal vaccine is placed on the vial cap. **True/False.**

Q7: Pneumococcal vaccine should be kept at 2-8 °C in the refrigerator. **True/False.**

Q8: Heat and freeze sensitivity of vaccines:

a) Which vaccines are highly heat sensitive in the EPI program in Ethiopia; write them in their heat sensitivity order starting from the most heat sensitive?

b) Which vaccines are freeze sensitive write them in their freeze sensitivity order starting from the most freeze sensitive?

Q9: In Kokeb health center, Belay, the person in charge of the refrigerator, one morning found that two pentavalent, three PCV-10 and one TT vial were frozen solid. He has also observed white sediments attached inside the other two vials of pentavalent vaccine, white sediments were attached on the glass walls and the rest (pentavalent, PCV-10 and TT vaccines) were in liquid form. The reading of the thermometer of the refrigerator was +2°C

a. Mention all possible causes of the problem
b. Discuss all the actions, step by step, that Belay should take.

3 Adverse Events Following Immunization

3.1 Definition

An adverse event following immunization (AEFI) is medical incident that takes place after an immunization, causes concern, and is believed to be caused by immunization (but not necessarily caused by immunization).

Although vaccines used in the Ethiopian Immunization Programmes are safe and effective, however, no vaccine is perfectly safe and AEFI can occur following any immunization. AEFIs are usually classified into five categories as described in below

Causes of AEFI	***Description***
Vaccine reactions	*Events caused or precipitated by vaccine and is caused by the inherent properties of the vaccine*
Programme error	*Event caused by an error in vaccine preparation, handling or administration*
Injection reaction	*Event from anxiety about, or pain from the injection itself rather than the vaccine*
Coincidental	*Event that happens after immunization but is NOT caused by the vaccine i.e. a chance association*
Unknown	*Event' cause cannot be determined*

3.2 Classification of AEFIs

3.2.1 Vaccine reactions

Vaccine reactions are adverse events caused or precipitated by the vaccine and may be classified into (a) common, minor reactions or (b) rare, more serious reactions. **Most vaccine reactions are minor and resolve on their own.** The more serious reactions are very rare and in general do not result in long-term problems.

Common, minor vaccine reactions	***Rare, more serious vaccine reactions***
1. Local reactions *a. Redness at injection site* *b. Pain* *c. Swelling* *2. Fever < 38.5°C.* *3. Irritability* *4. Malaise* *5. Generalized apathy* *These symptoms result from normal body immune response reaction to a vaccine or its components.*	*1. Convulsions* *2. Anaphylactic shock* *3. Severe allergic reactions* *4. Adenopathy* *5. Encephalopathy*

Pneumococcal vaccine reactions:

a) **Mild reactions**

Mild reactions have been reported in 10%–20% of children receiving the vaccine: local reactions such as swelling and tenderness at injection site are common occurring at about 1 in 2; systemic reactions such as irritability and crying are very common; and transient fever >39˚C occurs in about 1 in 20.

b) **Severe reactions:**

These include rare allergic reactions (dermatitis) which occur in 1 in 1,000

Contraindications:

PCV should not be administered to children with a known severe hypersensitivity reaction to a previous dose of the vaccine.

3.2.2 Programme Errors

Most of the reported AEFIs are related to programme errors than any other cause. The causes of errors are listed in Table 5. Vaccines are very rarely contraindicated. However, it is important to check for contraindications to avoid serious reactions. For example, vaccines are contraindicated if there is serious allergy to the vaccine or its components. Live vaccines should not be given to immune-deficient children.

Table 5. Common programme errors and associated events

Programme Error	***AEFI***
Non-sterile injection • *Reuse of disposable syringe or needle* • *Handling mixing or injection needles improperly* • *Contaminated vaccine or diluents* • *Use of vaccines beyond discard point*	*Infections* • *Local suppuration at injection site* • *Abscesses* • *Cellulites* • *Systemic infections* • *Toxic (septic) shock syndrome* • *Blood-borne infections*
Improper vaccine preparations • *Vaccine prepared incorrectly, including reconstituted with wrong diluents* • *Drugs substituted for vaccine* • *Wrong amount of diluents used* • *Inadequate shaking of vaccines before use.*	• *Local reaction or abscess* • *Effects of the drug (e.g. muscle relaxant, insulin)* • *No protection after vaccination with non-potent vaccine*
Improper vaccine injection: wrong site • *Subcutaneous instead of intra dermal BCG* • *Too superficial toxoid vaccines (TT, DPT etc.)* • *Injections into buttocks* • *Injection of too much vaccine*	• *Local reactions* • *Sciatic nerve damage*
Improper transport/storage • *Vaccine frozen incorrectly* • *Vaccine expired/VVM stage III/IV*	• *Local reaction from frozen (and ineffective) vaccines* • *No protection after vaccination with non-potent vaccine*
Contraindications ignored	• *Avoidable severe vaccine reactions*

Programme errors can be avoided by observing the following;

1. Reconstitute vaccines with the appropriate volume of diluents from the same manufacturer.
2. Correct application of multi-dose vial policy. (Discard PCV, measles and BCG vaccines after six hours or at end of session, whichever comes first)
3. Do not store anything else in the vaccine fridge except the vaccines and diluents
4. Use only AD-syringes and needles and one mixing syringe per vial for reconstitution of measles and BCG vaccines.
5. Inject vaccine in the proper site and depth (subdermal, subcutaneous, and intramuscular) at all times.

3.2.3 Injection Reactions

Injection reactions are reactions associated with anxiety related to injection. These can occur prior, during or after the injection. Injection reactions can be prevented by reassuring the recipient prior to the injection.

3.2.4 Coincidental AEFIs

These are events caused by something other than programme errors and individual reactions to vaccine. A coincidental event means that the medical incident would have occurred even if the individual had not been immunized. Coincidental events are unrelated to immunizations or vaccines in any way except for the time that they occur.

The best evidence to support a conclusion that a medical incident is coincidental is that the same event has been diagnosed in people who have not been immunized.

3.2.5 Unknown Causes of AEFIs

One other classification is helpful: “unknown” - for events with an unknown cause after investigation by appropriate authorities.

3.3 Management of Common Reactions

Advice on managing the common reactions should be given to parents, as well as instructions to return if there are more serious symptoms. This will help to reassure parents about immunization and prepare them for these common reactions.

Paracetamol, at a dose of up to 15mg/kg every four hours with a maximum of four doses in 24 hours, is useful for the common minor reactions. It eases pain and reduces fever. Paracetamol can also be used at the time of pentavalent vaccination to prevent fever.

A feverish child can be cooled with a tepid sponge or bath, and by wearing cool clothing. Extra fluids need to be given to feverish children. For a local reaction, a cold cloth applied to the site may ease the pain.

3.4 AEFI Surveillance

The major goal of immunization safety surveillance is early detection, appropriate and quick response to adverse events in order to lessen the negative impact on the health of the individuals and on the immunization programme. It is a key indicator of programme quality and enhances programme credibility by providing actual country data on vaccine risks. Refer to the AEFI guidelines for further information.

3.4.1 Which AEFI should be reported?

There is no point in reporting common minor reactions such as local reactions, fever, and self-limiting systemic symptoms. These are expected to occur and if reported, the volume of reports would overwhelm the system while contributing information of limited value. It is therefore important for health workers to advise the caretaker at the time of vaccination that these reactions are expected, and advise them on how to manage these common minor reactions (e.g. paracetamol to treat fever). For more serious problems, the caretaker should be advised to return or seek medical attention. More importantly, they should be advised not to delay treatment of a coincidental illness falsely attributed as a vaccine reaction.

Severe local reactions (e.g. swelling beyond the nearest joint; pain, redness, and swelling of more than 3 days duration; or requiring hospitalization), especially if occurring in clusters, should be reported. Local reactions occurring at increased frequency, even if not severe, should also be reported. They can be markers for programme errors or for problems with specific vaccine lots.

The following incidents should be reported and investigated:

1. ***All injection site abscesses***
2. ***All cases of BCG lymphadenitis***
3. ***All deaths that occur within one month of an immunization***
4. ***All cases requiring hospitalization that occur within one month of an immunization***
5. ***All medical events believed to be caused by immunization and about which people are concerned.***

Deaths and hospitalizations should receive immediate attention and should be reported as soon as they are detected. Abscesses, lymphadenitis, and other AEFIs should also be reported immediately if they are causing community concern. Immediate reports may be made by telephone, which gives supervisors an opportunity to assess the validity of data without delay.

All AEFIs, including those reported immediately during the month, should be counted in routine, written, monthly surveillance reports

3.4.2 Barriers to reporting

Peripheral health workers may not report AEFI for one or more reasons. Health workers should avoid taking part in the following behaviors which will result in poor reporting:

- Not considering the event as related to immunization.
- Not knowing about the reporting system and process.
- Lethargy- lack of interest or time
- Lack of reporting form.
- Fear that the report will lead to personal consequences.
- Guilt about having caused harm and being responsible for the event.
- Difference about reporting an event when not confident about the diagnosis.
- Lack of accountability

Health workers must be encouraged to report adverse events without fear of penalty. It should be clear to both the supervisors and the health workers that the aim of reporting is to improve systems or provide further training and not to blame individuals.

3.5 AEFI Investigation

The ultimate goal of a case investigation is to find the cause of an AEFI or cluster of AEFIs and correct it. Use the standard AEFI investigation form which is available in the National AEFI guideline

The purpose of investigating AEFI cases is the following:

1. To confirm a reported diagnosis or propose other possible diagnoses.
2. To identify the specifications of the vaccine implicated.
3. To examine the operational aspects of the programme.
4. To determine whether a reported event was a single incident or one of a cluster and, if a cluster, where the suspected immunizations were given and what vaccines were used.

Investigation should begin as soon as possible; ideally within 24 hours of detection by a health worker, to identify any programme errors that might be present, to correct them before other people are exposed to the same error, and to show members of the community that their health and concerns are taken seriously.

An AEFI investigation follows standard epidemiological investigation principles. In addition, investigation of the vaccine(s), administration techniques, procedures and service in action should be conducted. Three tools are available to gather information: the event description report (Annex 1), the AEFI case investigation report (Annex 2) and the line list (Annex 3).

AEFI detection, investigation, and analysis must lead to action if the credibility of immunization services is to remain high. These actions include diagnosis, treatment, reporting, communication and correction of programme errors. The different levels of the health system have different responsibilities. The peripheral health workers including the health extension workers are responsible for treating the patient, communicating with the parents and the community, responding to rumors or public enquiries and to fill out the case investigation form. The woreda health office and zone health departments are responsible for training, supportive supervision and communication to public using different modalities. All levels need also to take remedy for the identified adverse event in terms of improving logistics and providing training to identified skill problems. A summary of actions to be taken for different types of AEFI's is shown below.

Table 6: Recommended actions for AEFI

Type of AEFI	Action to be taken
Vaccine reaction:	If a higher reaction rate than expected is observed from a specific vaccine or lot then obtain information from the manufacturer and consult with WHO to consider: • withdrawing that lot • changing manufacturing specifications or quality control • obtaining vaccine from a different manufacturer.
Programme error:	Correcting the cause of the error. This may mean one or more of the following: • change in logistics for supplying vaccine • change in procedures at the health facility • training of health workers • intensified supervision. Whatever action is taken, it is important to review at a later date to check that the programme errors have been corrected.
Coincidental:	Main task is communication to ensure that people are persuaded that the link is just coincidental. This communication can be challenging when there is widespread belief that the event was caused by immunization. Sometimes, it may be useful to enlist further expert investigation to convince/ensure that the event truly was coincidental. The potential for coincidental events to harm the immunization programme through false attribution is immense.
Unknown	Depending on the nature of the event, its extent and whether it is ongoing, a further investigation by an expert may be needed. However, it must be accepted that in some cases the relationship to immunization is not clear.

3.6 Exercise

1. Define Adverse Events Following Immunization
2. List the types of AEFI
3. What are the potential vaccine reactions associated PCV?
4. How do you manage minor and serious AEFI?
5. What is the role of HW/HEW in the AEFI surveillance?
6. List the formats that are used in AEFI surveillance
7. List the steps for investigation of a case or cluster of AEFI

Case study

A child develops a severe allergic reaction with in 2 hours of receiving PCV, what are the immediate, short term and long term actions for the management of this child?

4 Communication

4.1 Definition

Communication is defined as transfer, exchanging and sharing of ideas, opinions, feelings etc between or among people at a given time to create common understanding and action.

4.2 Benefits of communication

- To create awareness and demand for pneumococcal vaccine.
- To create trust
- To reduce dropout rate and improve immunization schedule follow up
- To enhance early detection and reporting for pneumococcal vaccination adverse events.
- To avoid rumors and misinformation regarding PCV10
- To build strong community support for the immunization program
- To bring positive attitude change on immunization

4.3 Strategies for Communication

- **Advocacy:** to create awareness and commitment of decision makers at all levels to effectively support and facilitate the introduction and implementation of the vaccine in the country.
- **Social Mobilization:** To involve partners and stakeholders, social mobilizers, etc, in awareness creation and resource mobilization activities.
- **Program communication**: To create awareness and change behavior and call for action of the communities/mothers and care takers through training/ Workshops, interpersonal communication, group communication, mass media and preparation and distribution of communication materials etc.

The major communication activities that are expected to be undertaken using the above mentioned strategies are summarized in the table below.

Table 7: Advocacy and Communication activities for PCV introduction, Ethiopia

S.No	Strategy	Regional	Zonal /Woreda	Health center/Health Post
1	**Advocacy**	- Joint and separate advocacy meeting with the Regional President and Cabinet, - Joint and separate advocacy	- Joint and separate advocacy meeting with Administrators and Cabinet - Joint and separate	- Advocacy meeting with the Kebele administrators - Separate and joint

		meeting with education, information and communication Affairs, women and children Affairs Bureau heads, regional Religious institutions, - Joint and separate meeting with NGOs	advocacy meeting with Heads of Zonal/Woreda Education, Information & Communication Affairs, Women and Children Affairs Offices, Religious and Traditional Leaders - Separate or joint meeting with NGOs	advocacy meeting with school leaders, women and youth group Religious and traditional leaders, NGOs etc
2	**Social Mobilization**	- Conduct launching ceremony - Conduct rally or any special events on immunization - Prepare short social mobilization messages for schools, religious and traditional institutions - Plan and facilitate different social mobilization activities in school, religious and traditional institution - Use mobile vans to mobilize public - Prepare and install billboards - Prepare and display banners	- Conduct launching ceremony - Conduct rally or any special events on immunization - Prepare short social mobilization messages for schools, religious and traditional institutions - Plan and facilitate different social mobilization activities in school, religious and traditional institution - Use mobile vas to mobilize public - Prepare and install billboards - Prepare and display banners	- Conduct House to house announcement using social mobilizers and community Volunteers - Facilitate and give group education in school, church, mosques and other public gathering - Facilitate immunization rally of school children - Facilitate kebele public meeting on Immunization with the administrator
3	**Program Communication**	- Conduct trainings on communication, - Disseminate short messages and educational programs on Immunization, through mass media (radio and TV) - Prepare and distribute IEC materials /brochures, leaflets, posters, flipcharts, banners, billboards, etc -Support communication materials development & communication trainings organized by NGOs and other partners	- Conduct trainings on communication /Interpersonal communication/ - Prepare and distribute/ display IEC materials - Facilitate student quiz competition on PCV.	-Conduct interpersonal communication with clients - Distribute/display IEC materials - Conduct group education in the health post and outreach session

4.3 Interpersonal Communication

Health workers are conducting all types of communication mentioned above, however due to their frequent contact with mothers especially during immunization session, their role as interpersonal communicators on pneumonia and PCV 10 are given due consideration in this training manual.

Health workers should spend time with the caregiver to explain the immunization schedule, re-assure them about the benefits of immunization, explain possible side-effects and answer any questions they may

have.

Interpersonal communications skills are so important when interacting with your client. Do the following during interaction with the client at a vaccination session:

Welcome:

- ✓ *Greet the mother and infant when they come for vaccination. Ask her about the general health condition of her child and advise accordingly.*

Explain/ discuss

- ✓ *Inform the mother about the vaccines the child is going to receive and the diseases they protect against.*
- ✓ *Explain that there is no harm in giving multiple injections at the same time and reassure her that pain from two multiple lasts only a few seconds.*

Vaccinate:

- ✓ *Congratulate her for the patience and support she had during the injections.*
- ✓ *Inform her when and where to bring the child for the next vaccination session.*
- ✓ *Ask the mother if she has any questions or concerns*
- ✓ *Ask her whether you answered her questions or not. If not, answer again.*
- ✓ *Advise her to keep the immunization card in a safe place and to bring it during the next scheduled vaccination session for her child.*

Remind:

- ✓ *Tell her that the vaccine may cause a mild reaction, including fever or a local reaction (swelling, hotness and redness where the child had the injection).*
- ✓ *Reassure her that serious side effects are rare but should they occur, the child should be taken to the nearest health facility.*

Tips on communication

- ✓ *Tell the mother that if the child is not vaccinated he/she will be left unprotected and risk getting sick from Pneumonia*
- ✓ *Listen carefully, demonstrating that you are interested in what the mother has to say,*
- ✓ *Summarize what the client said to show you have understood and answer all her questions.*
- ✓ *Use simple and non-technical words when giving information and answering questions.*
- ✓ *Make the mother/child comfortable while administering the vaccine or recording. Show loving and caring gestures to her child.*

Farewell:

- ✓ *Try to comfort the child demonstrating love and care*
- ✓ *Provide a warm farewell to the mother in a culturally appropriate manner.*

Key messages on PCV

The following key messages are targeting caretakers and can be communicated in a group session /meeting, such as with community/traditional leaders, vaccination sessions (in health facilities and outreach sites), and community members in a group.

Pneumonia is:

1. *A leading killer of children under 5 years old in Ethiopia.*
2. *An airborne disease which spreads from person to person e.g. through coughing and sneezing.*
3. *Can be prevented by vaccinating children with the pneumococcal vaccine.*

PCV is:

1. Safe, effective and provided free of charge in public health facilities in Ethiopia.

2. Given to a child three times before the age of one year at 6, 10, 14 weeks.

3. Given at the same session with pentavalent vaccine. Pain and discomfort for the child to receive two injections at the same time may be experienced, but the benefits outweigh the risks of contracting and managing pneumococcal diseases

4. May cause a mild reaction, including a fever or a local reaction (swelling, hotness and redness at the injection site). Serious side effects are rare but should they occur, the child should be taken to the nearest health facility

Remember

A child's immunity against pneumonia can be improved by exclusive breastfeeding during the first 6 months of the child's life, good nutrition, reducing overcrowding and hand-washing with soap

Group Exercise on Communication

1. **Role play on immunization session**

A mother brings her 6 weeks old child to an out reach session. The Health Extension Worker (HEW) assesses the vaccination status of the child and notes that the child has only received BCG vaccine. The HEW informs the mother of the vaccines that child is to receive. However, the mother is hesitant to have her child receive more than one infection. Prepare a role play demonstrating interpersonal communication between HEW and mother during immunization session.

2. **Role play on responding to mother whose child has developed AEFI**

Prepare a role play on how to address the AEFI situation described below.

A mother and father come to one health center/post complaining that their child who received PCV two days ago developed some illness, which was not there before. Both of them are angry and shouting. The father believes that bringing their healthy child for vaccination was a great mistake and regrets allowing his wife to take his healthy child for vaccination.

5 Monitoring, Evaluation and Supervision of PCV Introduction

Introduction of a new vaccine may pose some new challenges in service delivery. To ensure an efficient introduction process, monitoring activities are required to assess data, procedures and practices in order to identify problems, develop solutions and guide interventions. , Supervision increases quality of implementation of activities by guiding, supporting and assisting service providers to carry out their duties to achieve the programme objectives. Evaluation activities provide an opportunity to assess the overall program status: performance, effectiveness and efficiencies, in order to improve the current and future processes.

5.1 Monitoring

Monitoring the introduction of PCV introduction may be done through:

- Regular (weekly) coordination meetings by the EPI focal persons and Coordinating Task Force members to verify that all the introduction activities are occurring on time in a quality manner
- Regular monitoring of immunization data, specifically PCV doses administered and vaccine stock to identify achievements and gaps that need to be addressed.

The introduction of PCV into the immunization program occurs at a time when the new Health Management Information System (HMIS) is being updated and rolled-out. These simultaneous activities are a challenge to the introduction as PCV requires HMIS support to update recording and reporting formats. The new HMIS will include PCV doses in the reporting and recording formats, however, in the event that HMIS is not fully rolled-out, a parallel recording structure will be required for the reporting during the first 3 months following the introduction of PCV.

5.1.1 Basic Recording Tools

Recording tools are necessary to ensure that each child receives the appropriate number of doses of vaccine, and monitoring tools to track progress. The introduction of PCV will require reporting on the standard EPI recording tools:

- EPI Registration Book
- Tally Sheet
- Immunization Card
- Family Folder

To monitor pneumococcal vaccination during and after introduction:

- Recording formats will be updated by the FMOH
- The new HMIS will collect PCV1 and PCV3 data as indicators
- For children who do not have updated an immunization card or are already in an existing EPI registrar, doses of PCV will need to be recorded into the existing format.

Note: It cannot be assumed that a child received PCV1 because they have received Penta1/OPV1, as some children will not present for PCV1 until after they have received their first dose of Penta1/OPV1.

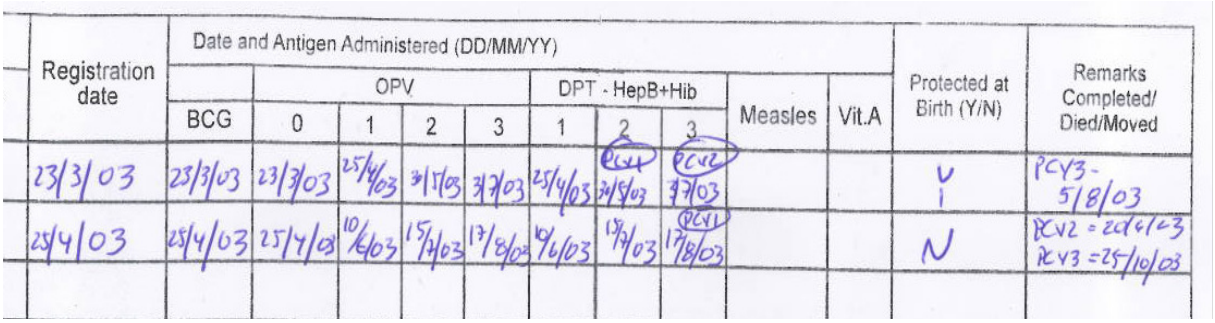
EPI Registration Book and Family Folder

The following tools will be utilized for recording the child's vaccination status at the vaccination site:

- EPI Registration book:
    - In the new book, the date PCV was administered should be recorded in the appropriate box. (see Annex 4)
    - In the old book (e.g. for children who already started vaccination), the dates when PCV was given should be marked with PCVX (X indicates the dose in the 3-dose series) in the DTP-HepB-Hib columns, and finally in the comments column (Figure 7)

- Family Folder
    - A form will be provided for insertion in the family folder, indicating PCV doses received and other health information.

An updated EPI registration book will be supplied to all health facilities for recording vaccination status of children in the catchment area. Once the new book is received, it is not necessary to enter the names of children who have already been entered in the pre-PCV register (the "old" EPI register used prior to introduction) into the EPI registration book. However, if it is found more convenient, it is acceptable to transfer those who have not yet been fully immunized into the new book. If this is done, it is necessary to indicate in the "Remarks" column of the EPI register (the last column), that the child is found in both the pre-PCV and the new registrar. In the pre-PCV registrar note "transferred to new reg", and in the new register write "transferred from old reg."). If the child is only in the new book, no comment is needed.



Registration date	Date and Antigen Administered (DD/MM/YY)										Protected at Birth (Y/N)	Remarks Completed/ Died/Moved
	BCG	OPV 0	OPV 1	OPV 2	OPV 3	DPT - HepB+Hib 1	DPT - HepB+Hib 2	DPT - HepB+Hib 3	Measles	Vit.A		
23/3/03	23/3/03	23/3/03	25/4/03	31/5/03	3/7/03	25/4/03	31/5/03 (PCV2)	3/7/03 (PCV3)			Y	PCV3 - 5/8/03
25/4/03	25/4/03	25/4/03	10/6/03	15/7/03	13/8/03	10/6/03	15/7/03	13/8/03 (PCV3)			N	PCV2 = 20/6/03 PCV3 = 25/10/03

Figure 7- Sample pre-PCV version of EPI Registration Book indicating how PCV doses can be noted. New children should be registered in the updated EPI registration book when it becomes available.

Like the previous register, the updated EPI Register will require recording of the date each PCV dose is administered. It is necessary to record the date each vaccine is given (PCV, Pentavalent and OPV) and not assume PCV was given if Pentavalent was given, as there will be situations where not all doses were given, for example stock-outs of one vaccine, but not others.

The EPI registration book can be used to identify defaulters. Children who have not yet received all three doses and those who have started the series, but not yet completed, should be traced. Vigilance to ensure all eligible children receive PCV is necessary, especially if doses do not follow the traditional 6, 10, 14 week schedule.

Immunization Card

All PCV doses should be recorded on the child's immunization card. Immunization cards are kept with the child to report their vaccination status, and other information, such as growth monitoring. The updated immunization card will clearly indicate where PCV dose received and date administered should be entered.

If a child already has an immunization card or a new immunization card is not available, the three PCV doses PCV1, PCV2 and PCV3 should be entered in the empty space on the card (see Figure 8). It is preferable to transfer the information from the pre-PCV card to the new card if a new card is available.

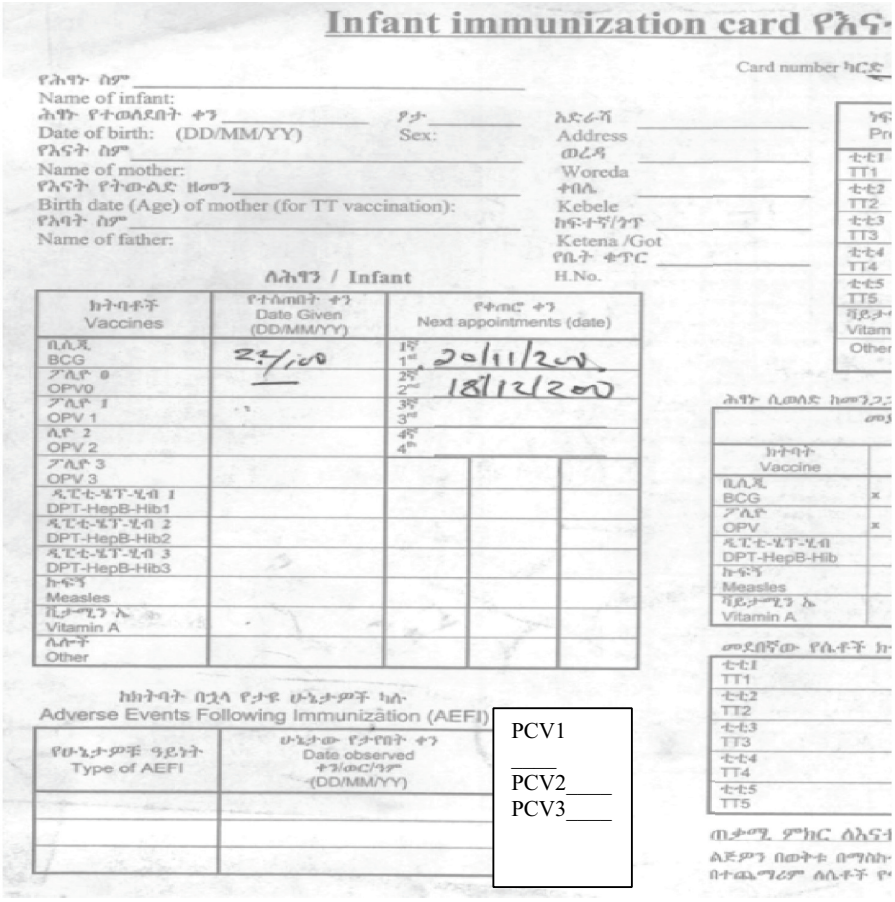


Figure 8- Sample Immunization Card indicating where PCV doses can be included if a new card is not available, or the child has already started their card.

Tally Sheet

It is recognized that many health posts do not have standard tally sheets. New tally sheets will be introduced that include PCV. If a new tally sheet is not available, the health facility will be required to include a line for PCV1, PCV2, and PCV3 on their existing tally sheet. This data will be required to be reviewed by supervisors, to evaluate several issues including vaccine demand. A copy of the updated tally sheet should be distributed during the training (Annex 5).

5.1.2 Vaccine Supply

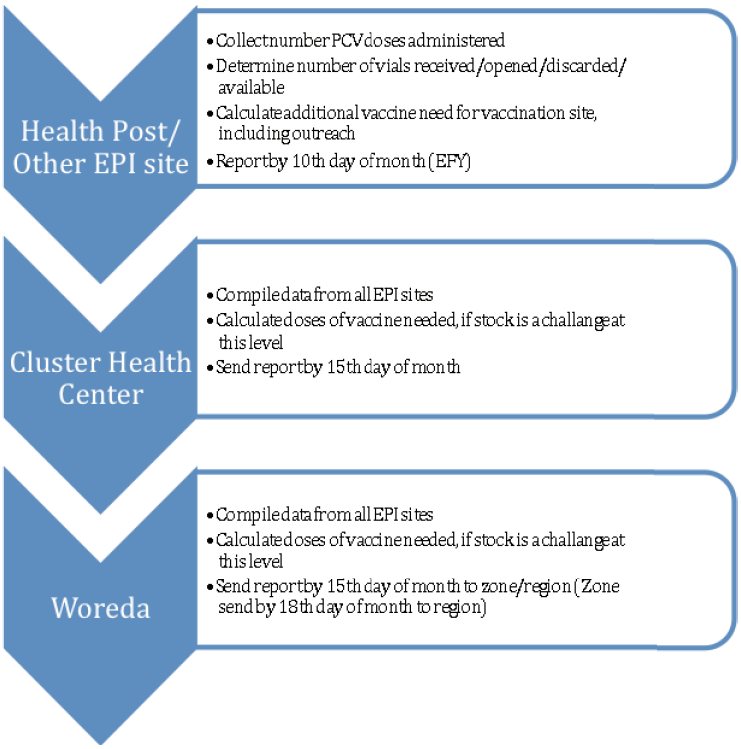
Monitoring of wastage and vaccine supply will be important during the introduction period, as well as in the future. Monitoring vaccine stock and wastage of the newly introduced new vaccine is important because:

- PCV will be given to children below one year old who have recently completed their DPT-HepB-Hib series, and therefore more children than expected may receive PCV vaccine, which may result in stock outs, therefore monitoring if vaccine is in excess (to share) or shortage (to request) will be necessary.
- Wastage rate of PCV is estimated, and may require re-evaluation, therefore, recording the number of doses used and vials used will be important.

$$Vaccine\ Wastage = \frac{Number\ of\ Doses\ Given}{Number\ of\ Vials\ Opened\ x\ Doses\ per\ vial}$$

Weekly monitoring for adequate stock levels is necessary. The target population for the first year of introduction is the annual number of surviving infants (those who are under one and eligible at the time of introduction) plus the number of surviving infants born after introduction. It is important to note, that in some areas the social mobilization for PCV may increase vaccine demand significantly enough that stock-outs of vaccines other than PCV may occur.

Reporting of Doses Administered and Vial Utilization



During the first six months of the introduction period, program managers will need to be more vigilant of the number of PCV doses administered, as well as other vaccines. A simple reporting form should be completed by each health facility for the first 3-6 months of introduction (this period may be extended until new HMIS formats are available).

The reporting format records the number of PCV and Penta doses administered from each health unit. These are shared through the EPI focal persons at the end of each month together with the routine (old) reporting form. In addition, in order to monitor PCV stock levels the number of PCV doses available is calculated. The reporting format is found in Annex 7 for health units and Annex 8 for reporting units. The Monthly report from health facilities should be submitted according to the normal HMIS schedule.

ock
so be
see Annex)

5.2 Supervision

The training provided to health workers and supervisors during the introduction as well the supportive documentation should provide adequate guidance for all staff to safely provide PCV to infants in Ethiopia; however, the best trainings still benefit from supportive supervision to reinforce the messages provided. Supervision requires all supervisors be fully acquainted with the training material and monitor appropriately including:

- Woreda EPI focal points providing supervision for each cluster health center, and HEW supervisors.
- HEW supervisors provide extra emphasis to immunization activities.
- All supervisors should place special emphasis on immunizations during the first 6 months following introduction (special supervision budget as been provided for this activity).

The supervisory visit should include a review of the monitoring data, injection practices, social mobilization, logistics, stock management and vaccine handling practices at the health post. In addition, the supervisor from the region/ zone should gather information for the monthly report. A suggested supervision Checklist is attached in Annex 10.

5.3 Evaluation

The introduction of PCV will require ongoing evaluation so as to address challenges and gaps, as well as to share successes. Monthly reports are requested from each sub-regional level (woreda in most regions, or zone from Amhara, Oromia and SNNPR). These reports should mention successes and challenges of implementation as well as utilization of PCV relative to Pentavalent vaccine during the same month of the current and previous year. All challenges should be listed. The information for this report should be gathered from supervisors. These reports should be compiled by the Region and submitted to the central level. A monthly report is expected at the FMOH by the 15th of the month for the first 6 months of introduction, this is to be submitted with vaccine.

Review meetings have been budgeted to occur at the zonal and woreda level on a quarterly basis, and at the regional level every 6 months during the first year following introduction. The review meeting should follow the same format as the monthly reports. The participants should include government (including logistics (PFSA), HMIS (Planning), Health Promotion, Disease Prevention), and partners involved in implementation on the ground, including IFHP, WHO, UNICEF, other NGOs providing health services.

In addition to these reports, a programmatic evaluation will be completed one, six and twelve months after introduction. This will be coordinated from the central level and is expected to supplement the woreda and regional evaluations. At the end of introduction, a national level review meeting will be held.

Format for Evaluation Report can also be used as a template for review meetings

- Achievements for proportion of target children reached during introduction of PCV
- Timeline of activities (training, arrival of vaccine, first use of PCV for vaccination, any other major events
- Members of planning/implementing task force (including title/JOB Title)
- Training
  - Quality of training
  - Reported gaps in training from participants
- Supervision
  - Frequency of visits
  - Major strengths identified
  - Major challenges indentified
- Social Mobilization
  - Involvement of administration
  - Assessment of community awareness
- Vaccine management/Cold Chain
  - Stock received/utilized/stored
  - Calculation of wastage rates
  - Health Worker exposure sessions (which ever is first)
  - Cold chain challenges (refrigerators, cold box, vaccine carrier)
- Reports of AEFI

Exercise:

Q1: During the first three months following PCV introduction, what are the most important issues to monitor (by HW, HEW and supervisors)? Select the single most appropriate answer.

a. Vaccine stock
b. Disposal of opened vials 6 hours
c. Reaching every child
d. Adverse events following immunization
e. All of the above

Q2: When should PCV be written into an empty space on a child health card. (select all appropriate answers)

a. If a child presents a card indicating they have already received DPT-Hepb-Hib1 but not PCV1
b. If a child presents without a card and no cards are available with space for PCV
c. If child health cards without a box for PCV are used
d. Never, all child health cards without PCV entry space should be copied to new child health cards.

Q3: Which vaccines should be included on a tally sheet (select all appropriate answers, not all vaccines that should be on the tally sheet are listed)

a. OPV1, OPV2, OPV3
b. OPV3 only
c. PCV3 only
d. PCV1, PCV2, PCV3
e. DPT-Hepb-Hib1 and DPT-Hepb-Hib3 only (not DPT-Hepb-Hib2)
f. DPT-Hepb-Hib1, DPT-Hepb-Hib2 and DPT-Hepb-Hib3

Q4: Which of the following topics should be discussed at Woreda, Zonal and Regional review meetings at the end of PCV introduction? Select all appropriate answers.

a. Achievements of PCV (coverage)
b. Challenges of the introduction and how they were addressed
c. Challenges to pneumococcal disease surveillance
d. Review of the quality of how the plan was implemented

Q5: Supervisory visits should include the following issues: (select all appropriate answers)

a. Cold Chain and vaccine handling
b. Vaccine stock management
c. Communication
d. Monitoring

Q6: Reports on the number of vials used at health facility level should be sent:

a. Daily
b. Weekly
c. Monthly
d. Quarterly

Q7: When vaccine stock are below 25% of monthly target at the health post, cluster health center or woreda level, the request for more vaccine should be sent

a. Immediately
b. Weekly
c. Monthly
d. Quarterly

Practical Exercise

1. Completion of Monitoring Chart

The target population of your catchment area is 360 children <1 year of age per year. Please complete the attached monitoring chart below, given the following information for the first 4 four months of the year. Unlike the monitoring chart used in the health post, plot the PCV3 doses administered as well.

Vaccine	Month1	Month2	Month3	Month4
DTP-Hepb-Hib1	20	45	10	30
DTP-Hepb-Hib3	30	36	42	24
PCV3	0	10	20	10
Measles	15	15	15	15

Discussion:
Assume introduction of PCV occurred in Month 12 of the previous year. Are there significant differences between DTP-Hepb-Hib3 and PCV3, why or why not?

2. Review of recording formats and instructions on how to complete each format.

- Tally Sheet
- EPI Register
- Immunization card
- Family Folder

6 Planning for PCV Introduction and Sub-National Level

During the training of Regional, Zonal and Woreda health offices staff, the first and a half days will be allocated for training and the second day for planning for the introduction of new vaccines in their respective region, zone and woreda.

The planning will include the following major areas:

6.1 Coordination

A Regional / Zonal new vaccine Coordination Committee will be established under the leadership of the RHB. Members of the Committee will include partners such as UNICEF, WHO, Clinton Health Access Initiative (CHAI), IFHP and other EPI partners. The Committee will coordinate all aspects of the introduction of the new vaccine and provide regular updates to the national level.

Two working groups will be constituted: Logistics and Communication, with technical experts from the different agencies. The working groups will be responsible for the detailed planning and implementation of the specific components of the introduction plan. See annex 11 for monitoring of the implementation of the new vaccine introduction plan of action.

6.2 Training

Training on new and underused vaccines has been part of the general training on EPI program at regional and zonal level and this needs to be further strengthened to be in form of cascade training at regional, zonal, woreda and health facility levels. See annex 12 and 13 for the proposed training agendas at each level.

The following trainings will be conducted:

- Training of Regional Health Bureau staff, Zonal health department staff and woreda health offices staff on the new vaccines introduction for two days

Training of health facility staff will include a minimum of two staff from each hospital and health center and all health extension workers in the region. Hospital and health center staff will be trained for two days. HEWs will be trained for one day. The trained health worker from each facility will be required to brief other staff at their health facility of assignment.

6.3 Assessment and planning for adequate cold storage capacity

Regional health bureaus, zonal health departments, woreda health offices and health facilities should plan for cold storage space for PCV and other vaccines. PCV10 needs a storage space of 4.8cm3 per dose.

The assessment of cold chain storage space at health facilities from the inventory conducted in 2008, indicated that the introduction of the pneumococcal and rotavirus vaccines can be accommodated with the exiting type of refrigerators in health facilities. However, as the cold chain inventory data is more than two years old coupled with the fact that the process of updating of inventory information has been inconsistent across the country, the current status of the refrigerators is unknown.

The following major activities will be planned and accomplished to ensure the adequacy and functionality of the cold storage space:

- Conduct cold storage capacity assessment at all levels
- Distribute available and new cold chain equipments based on the cold chain assessment results and recommendations

- Ensure availability of internal thermometer and temperature monitoring tools to all cold chain equipments
- Ensure contingency plan development in case of cold chain storage break down or space problem or power failure at all level during the training
- Plan for availability of power source e.g. kerosene at health facility level

Estimation of adequate quantity, collection and distribution of the new vaccines, injection devices, the revised guidelines and formats

- Plan for adequate quantity of PCV and injection materials
- Develop a distribution plan of vaccine and other materials
- Avail transportation facilities from the regions to the Woreda level
- Follow up smooth distribution of the new vaccine to Woredas and HFs

Cold chain equipment maintenance

- Develop maintenance plan and implement
- Strengthen the maintenance system through providing maintenance tool kits
- Conduct cold chain maintenance at all levels

6.4 Injection safety and waste management

All immunization services are provided using AD syringes and safety boxes and trainings will be given to service providers on injection safety.

About 32% of public health facilities have locally designed one-chamber incinerators, where sharps and other healthcare wastes are disposed by burning. The remaining health facilities use dug pits as a means of waste disposal. Training, sensitization and supervision will continue at all levels to improve waste management.

6.5 AEFI Monitoring

AEFI surveillance training will be conducted for all health workers in EPI integrated with the PCV introduction training. The potential AEFI that can occur due to program errors will be described in the national AEFI surveillance guideline along with precautions to avoid the problems. All levels should plan for AEFI surveillance and monitoring.

6.6 Advocacy, social mobilization and program communication at all levels

The advocacy needed to help policy makers decide on introducing new vaccines was very successful and there is a need for similar advocacy to ensure sustained interest and support on the part of Government and partners. Social mobilization is another strategy to get participation and support of important stakeholders for the program. On the other hand, a number of program communication activities should be conducted targeting care takers to bring their children for vaccination. For this to happen, due consideration should be given for development of appropriate communication strategies and action plan. Some of the activities to carry out will be for a short time while others will be continuous.

Below is an outline of some of the activities envisaged to support the introduction and will be included in the

plan of action at all levels:

- Conduct high-level advocacy meetings with leaders of key religious-based agencies
- Media campaign which includes IEC material production
- Launching ceremony in the presence of high-level officials.
- Produce, pre-test and broadcast new vaccine introduction radio spot messages in local languages as to raise the span of reaching key policy and decision makers, religious and influential community leaders. Using regional educational radio stations, new vaccine can be introduced to the school community and through them a wider community can be reached.
- Conduct community meetings on the introduction of the new pneumococcal vaccine in sample selected communities of densely populated regions and record and broadcast the proceedings on radio and TV to have a multiplying effect on other areas of the country.
- Conduct radio and TV discussions involving professionals and representatives of partners/allies, including community representatives.

6.7 Supportive supervision, monitoring and review meeting

Currently supportive supervision to the district and health facility levels is ongoing by Regional Health Bureaus and zonal health departments. The regions should plan for regular supportive supervision at all levels.

- Regular reports are expected from all levels on the progress of activities.
- Regular supportive supervision visits and on job training will be conducted by all levels.
- Review meetings will be conducted every six months at regional level and quarterly at zonal and woreda level.

7 Frequently Asked Questions

1: Why is it that only children below one year of age are receiving this vaccine in Ethiopia?

Despite the fact that children aged below 5 years are most vulnerable to pneumococcal diseases, the burden of pneumococcal disease is highest in children below one year. In introducing this vaccine, the government has decided to vaccinate children at the earliest opportune time i.e. below one year.

PCVPCV2: Is it safe to give my child two vaccine injections at the same time?

Yes. The pentavalent and PCV given at the same time are safe and effective for protecting against the two most common and serious microorganisms causing childhood pneumonia and meningitis.

The pain your child may experience with two injections is no greater than when the injections are given during separate visits. In addition, when the two injections are given during a single visit, the minor side effects that may occur will be reduced to a single episode.

3: Are there any side effects for this vaccine?

This vaccine is safe. Occasionally children vaccinated with this vaccine may develop a mild fever or a local reaction (swelling, redness, hotness, where the child had the injection). Notably, most children get better quickly. However, if the side effects persists, please take them to the nearest health facility.

4: Will it make a difference if my child isn't immunized at 6, 10 and 14 weeks? Does the timing really matter?

Timing matters. Ethiopia's immunization schedule is developed to ensure that children are immunized at a time when they are most at risk of disease or complications. Your child must receive all the vaccinations necessary at the time when they most need them. Not having the vaccinations as scheduled may put your child at risk of contracting diseases.

However, do not hesitate to bring your child for vaccination even if they are late. The child is still eligible if they are under one year of age.

5: My child is sick today. Is it okay for them to have the immunization?

Mild conditions like a common cold should not be regarded as contraindications for vaccination with this vaccine.

Only children with severe illness, as determined by a health worker (e.g. fever ≥39°C) should wait until their condition improves before being vaccinated.

6: How do I know if my child has pneumonia?

Symptoms of pneumonia may include cough, fever, difficulties in breathing. Always take your child immediately for assessment by a qualified health professional. Early treatment of pneumonia can

prevent serious complications and death, even in children who have received all their vaccines.

7: After my child is vaccinated with this vaccine, can they still contract pneumonia?

The organisms that cause pneumonia are multiple. This vaccine will protect your child against the most severe types of pneumonia. There is a small risk of your child contracting other forms of pneumonia but this risk is lower compared to children who are not vaccinated with this vaccine.

8: My child is HIV positive, should he/she be vaccinated with this vaccine?

HIV positive children are at high risk of pneumococcal pneumonia. The child should receive the vaccine on time as it is safe to be administered to HIV positive children.

PCV 10 Summary

Disease(s) prevented by the vaccine	Pneumococcal diseases (meningitis, pneumonia, other invasive diseases) caused by vaccine serotypes*:* *1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F*
Type of vaccine	Polysaccharide-protein conjugate vaccine (vaccine does not contain any live bacteria). PCV10 contains 10 serotypes and is available in the EPI as a two dose preservative free liquid
Dose, route and site of administration	0.5 mls by intramuscular (IM) injection into the right outer upper thigh
Presentation and vial size	A single dose vial is available and has recently been pre-qualified by WHO. A two-dose preservative-free fully liquid presentation has also recently been pre-qualified by WHO.
Target age group	Infants (under 12 months of age)
Number and schedule of doses	3 doses administered at 6, 10 and 14 weeks
Contraindications	Known hypersensitivity to a prior dose Infants with a moderate or severe illness (temperature ≥39°C): delay vaccination until the child improves
Adverse reactions	Local reactions (redness, pain and swelling); fever
Co-administration with other vaccines or child health intervention	Can be safely co-administered with other EPI vaccines
Wastage rate per vial size	Wastage for two-dose vial is maximum 10%.
Storage conditions: heat and freeze sensitivity	2-8°C. Do not freeze. The volume per dose is 4.8cm^3
Proposed or recommended approach for surveillance and monitoring	Sentinel surveillance for invasive pneumococcal disease

Annex 1. AEFI Event Description Report Form

Demographic details:

Name _____ Sex _____Date of birth ___/__/__

Region_____Zone_____Woreda_____

Kebele_____Gott/ Ketena_____

Health facility _____ Name of health worker reporting _____

Vaccine(s) given	Route	Site	Lot number	Manufacturer	Expiry date

Date suspected vaccine given	Date of onset of AEFI started	Onset interval from administration	Date AEFI reported

Tick box(es) and describe event:	**Past medical history (including history of similar reaction or other allergies) and any other relevant information (e.g. other cases):**
Toxic shock syndrome Sepsis Abscess: sterile bacterial Lymphadenitis: > 1.5 cm or draining sinus Severe local reaction: > 3 days beyond nearest joint or hospitalized Vaccine reaction on list (state): Other AEFI(state):	
Recovered Yes / No ? Hospitalized Yes / No? Died: Yes /No?	

Woreda/Zonal level office to complete

Date report received:	**Checked by:**
Investigation needed:	**If yes, date started**
Investigator	**AEFI investigation ID**
Causality assessment:	**Certainty:**

Annex 2. AEFI Investigation Form

Complete this summary page at end of investigation; file with field report and AEFI report forms

Investigation ID_____	**AEFI report ID:_____**	**Date investigation started ____/____/____**
Describe trigger event:		
Diagnosis/ case definition of event:		
Community investigation with detail check list: Yes/No? if yes indicate result of investigation		
Clinical investigation with detail check list carried out? Yes/No? if yes, list key finding(s):		
Laboratory investigation (s) : if yes, mention activities and key results:		

Some Hints for categorization of AEFI

Programme error	**Vaccine reaction**	**Coincidental**	**Unknown**
• Non sterile injection	• Vaccine lot problem	• Rate Similar with unimmunized children	
• Vaccine prepared incorrectly	• Unknown vaccine reaction	• Others	
• Administration technique	• Others	•	
• Vaccine transportation and storage • Others	•	•	

Confidence about conclusion on main causes of AEFI: Certain Probable Possible

Reason (s) for conclusion:

Corrective action taken: Yes/No? if yes, specify

Further action recommended: Yes/No? if yes, specify

Investigator**:** _____ Signature _____Date _____/_____/_____

Annex 3. AEFI line listing form for compilation at districts or zonal level to identify trends and clusters of AEFI

Zone_____/Woreda _____/ HF: _____Month/Year: _____Date sent from District: _____

No. of HFs in District: _____No. HFs submitting: _____

No.	Patient's Name	Sex (M/F)	Date of Birth	Address / woreda/ kebele/	Vaccine Used	Batch/ Lot #	Expiry date	Date vaccine given	Vaccine given by*:	Date of onset	Type of AEFI**	Outcome ***	Investigated? (if Yes, date of investigation)	Comment

* Fill in the appropriate number: 1.Health Extension worker, 2.Front line h Health Worker, 3 Health Assistant. 4 Nurses. 5.Health officer, 6.Doctor, 7 .Other (describe)

** Fill in the appropriate number (if hospitalized for AEFI – include both numbers (e.g. hospitalized for seizures – record as follows: 4, 6)
1. Severe local Reaction, 2.BCG lymphadenitis, 3. Abscess, 4.Seizures, 5. Acute Flaccid Paralysis, 6 .Hospitalization, 7.High fever 8. Anaphylaxis 9. Death; 10. Other (describe)_____

*** Write any of the fol1owing: 1.Recovered, 2. Died, 3. Residual problem (describe)_____

Reported by: _____ **Signature: _____**

Designation: _____ **Date: _____**

Annex 4. Infant Immunization Registration Book

Personal information						Address				Registration	Antigens received																Neonatal tetanus protection			Growth Monitoring				
												OPV				DPT-HpB-Hib			PCV			Rota												
Serial No.	Infant's MRN (fill at HC/Hosp)	Name of infant	Date of Birth (DD/MM/YY)	Sex (M/F)	Name of mother	Woreda	Kebele	Gott	House No.	Reg. Date (DD/MM/YY)	BCG (DD/MM/YY)	0	1	2	3	1	2	3	1	2	3	1	2	Measles (DD/MM/YY)	Fully immunized by first birthday (√)	Mother received 2 doses of TT in last pregnancy (√)	Mother received a total of 3 or more doses of TT (√)	Protected at birth (PAB) (√)	Date (DD/MM/YY)	Weight (kg)	%WFA	Vitamin A (DD/MM/YY)	Remark/Appointment	
(1)	(2)	(3)	(4)	(5)	(6)	(8)	(9)	(10)	(11)	(12)	(13)	(14)	(15)	(16)	(17)	(18)	(19)	(20)						(21)	(22)	(23)	(24)	(25)	(26)	(27)	(28)	(29)	(30)	

Annex 5. Tally sheet for Hospital and Health Center Level

Woreda _____ Facility _____ Type of session static ____Outreach____
Year _____ Month _____

	Children immunization Doses given Doses given			
	Under one year		One year and older	
Antigen	**Tally**	**count**	**Tally**	**count**
1.BCG				
2.1 DPT-HepB-Hib1				
2.2 DPT-HepB-Hib2				
2.2 DPT-HepB-Hib3				
3.1 OPV0				
3.2 OPV1				
3.2 OPV2				
3.3 OPV3				
4.1 PCV1				
4.2 PCV2				
4.3 PCV3				
5.1 Rota1				
5.2 Rota2				
7.Fully Immunized				
7. Protected at birth from neonatal tetanus				
8. TT all doses				

Vaccine	No of open vials	Number of un opened discarded vials				
		VVM change	Expiry	Freezing	Breakage	Other
BCG						
OPV						
DPT-HepB-Hib						
PCV						
Rota						
Measles						
TT						

Annex 6. Health post service level all program tally sheet

A.3	Expanded Program on Immunization (EPI)		House numbers				
3.1	BCG for < 1yrs	BCG >=1yrs					
3.2	OPV0 for < 1yrs						
3.3	OPV1 for < 1yrs	OPV1 for >= 1yrs					
3.4	OPV2 for < 1yrs	OPV2 >= 1yrs					
3.5	OPV3 for < 1yrs	OPV3 >= 1yrs					
3.6	Penta 1 for < 1yrs	Penta 1 >=1yrs					
3.7	Penta 2 for < 1yrs	Penta 2 >=1yrs					
3.8	Penta 3 for < 1yrs	Penta 3 >=1yrs					
3.9	PCV1 for < 1yrs	PCV1 for >= 1yrs					
3.10	PCV2 for < 1yrs	PCV2 for > =1yrs					
3.11	PCV3 for < 1yrs	PCV3 for > =1yrs					
3.12	Rota1 for < 1yrs	Rota1 for > =1yrs					
3.13	Rota2 for < 1yrs	PCV1 for > =1yrs					
3.14							
3.15	Measles for < 1yrs	Measles >=1yrs					
3.16	Fully immunized for < 1yrs	Fully immunized >=1yrs					
3.17	Births protected against NNT (PAB)						
3.18	TT vaccinated all						
3.6	Vaccine	Opened	Discarded un opened				
			Expiry	Freezing	VVM change	Breakage	Other
3.6.1	BCG						
3.6.2	Pentavalent (DPT-Hep B -Hib)						
3.6.3	Polio						
3.6.4	Measles						
	PCV						
	Rota						
	TT						

Annex 7- Health Facility Reporting Format

Health Facility_____ Month _____			
Doses Administered			**Vials**
PCV1		PCV Vials Available at start of month	
PCV2		PCV Vials Received this month	
PCV3		PCV Vials Opened	
Total PCV		PCV Vials Available at end of month	
Penta1		Comments/Vaccine requests:	
Penta2			
Penta3			
Total Penta			

Annex 8- Cluster Health Center/Woreda Reporting Format

Region_____ Zone_____ Woreda_____
Cluster Health Center_____ Month _____

Doses Administered		Health Units Reporting	Total Health Units	% Report	STOCK MANAGEMENT Monthly Report	
PCV1						Vials
PCV2					PCV Vials available at start	
PCV3					PCV Vials Received	
Total PCV					PCV Vials Opened	
Penta1					PCV Vials available at end	
Penta2					Comments/Requests:	
Penta3						
Total Penta						

Annex 9- Regional/Zonal Reporting Format

Region_____ Zone_____ Month _____

Doses Administered		Health Woredas	Total Woredas	% Report	STOCK MANAGEMENT Monthly Report	
PCV1						Vials
PCV2					PCV Vials available at start	
PCV3					PCV Vials Received	
Total PCV					PCV Vials Opened	
Penta1					PCV Vials available at end	
Penta2					Comments/Requests:	
Penta3						
Total Penta						

Annex 10- Suggested Supervision Checklist

S/N	Question	Comment
	Monitoring	
M1	Are new tally sheets available and being used?	
M2	Are doses of PCV being recorded correctly?	
M3	Are new EPI registers available and being used?	
M4	Are EPI registers being used correctly?	
M5	Are new immunization cards available?	
M6	Are all HW and HEW trained on the administration of PCV?	
	Cold Chain	
CC1	Is adequate cold chain storage available (cold box/refrigerator)?	
CC2	Is the cold chain functioning (kerosene/ electricity available)?	
CC3	Is there adequate space for storage of vaccine for the supply period? (space between boxes)?	
CC4	Is refrigerator temperature recorded twice daily?	
CC5	Are freeze sensitive vaccines (DPT-HepB-Hib, TT, PCV) kept in a refrigerator away from the freezer compartment or from the place where the temperature that may cause freezing?	
CC6	Are ice packs properly conditioned for transportation or chilled water packs used?	
CC7	Is there a temperature record or/freeze tag showing temp below 0^{o}C?	
CC8	Does a random shake test on a vial indicate freezing? (if yes, report immediately to higher level to investigate).	
	Logistics and Vaccine Management	
L1	Observe- Are open vials of PCV in refrigerator?	
L2	What VVM stage are the PCV vials in (and other vaccines? (if multiple VVMs, estimate percent in each stage)	
L3	Are HW/HEW aware of disposal policy of PCV, (Dispose open vials after 6h from opening or end of session, whichever is first)?	
L4	Are adequate vaccine and supplies available	

	based on previous consumption?	
L5	Observe- Are adequate recording and reporting formats being used?	
L6	Observe- Are PCV Job Aids displayed on walls of the facility?	
Injection Practices		
I1	What is the greatest concern HW/HEW have about administering PCV?	
I2	Observe- Are multiple vaccines (e.g. PCV and Penta) being combined into a single syringe for a single injection?	
I3	Are waste disposals correct (use of sharps containers, and non-sharps in other receptacle)	
I4	IS there a place to dispose of sharp boxes (pit, incinerator)? (Observe if possible)	**Pit/Incinerator/Other:** **Adequate:** **Observed Y/N:**
Communications		
C1	What is the greatest concern mothers have about receiving PCV?	
C2	Observe- Are HW/HEW giving the appropriate messages to mothers?	
C3	Are PCV IEC materials available at the facility?	

Annex 11. PCV introduction sample plan of action

Activity	M1				M2				M3				M4				M5				M6				M7			
	Week				Week				Week				Week				Week				Week				Week			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Establish regional New vaccines introduction coordinating (NVI) coordinating committee	x																											
NVI coordinating committee weekly meeting	x	x	x	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	X	x	x	x	x
The PCV introduction POA developed and endorsed by ICC	x	x	x	X	x	x	x	x																				
Assessment of the functional status cold storage space at all levels				X	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x								
Orientation of PFSA and other regional level staff										x																		
Collection and distribution of revised EPI policy guideline, EPI recording and reporting guideline, AEFI Guideline, PCV training materials, communication materials																												
Training of regional level staff													x	x	X													
Zonal and woreda level staff trained														x	X	x	x	x										
Health facility and hospital staff training																				x	x	x	x	X				
Training of HEWs																					x	x	x	X				
Orientation of all staff and HEWs supervisors																												

Activity	M1				M2				M3				M4				M5				M6				M7			
	Week				Week				Week				Week				Week				Week				Week			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Advocacy and Social mobilization activities														x	x	x	x	x	x	x	x	x	x	X	x	x	x	x
Vaccines and other logistics distributed to all regional cold stores																				x	x	x	x	X				
Vaccines and other logistics distributed to woreda stores																				x	x	x	x	X				
Vaccines and other logistics distributed to all health facilities																					x	x	x	X	x	x		
Launching of PCV introduction																											x	
Supportive supervision and monitoring of PCV introduction at all levels																											x	x
PCV coverage monitoring and review meeting																											x	x

Annex 12. Agenda for EPI Managers and HWs Training 2011
Regional and Zonal level

Day 1:

Time	*Activities / Topic*	Responsible
8:30 - 9:00	Registration	
9:00 – 9.10	Objectives and expected outcomes	Regional/Zonal EPI FP
9:10 – 9:20	Opening speech	RHB/ZHD
9:20 – 10:30	Pneumococcal disease and PCV – Epidemiology, transmission, protection, prevention and treatment – Pneumococcal Vaccine	Supervisor
10:30 – 10:50	**Tea break**	Organizers
10:50 – 12:00	– Group work exercise, demonstration and video show on pneumococcal disease and PCV – Demonstration of vaccine, AD syringe and safety box	Supervisor
	Discussion	
12:30 – 2:00	**Lunch**	Individually
1:30-2:30	Cold chain and vaccine management – Cold chain, storage, vaccine forecast – Vaccine and stock management, cold chain monitoring tools	Supervisor
2:30 - 4:00	Exercise and video show on cold chain and vaccine management ○ Interpersonal communication ○ Key messages on PCV	Supervisor
4:00 – 4:200	**Tea break**	Organizers
4:20 - 5:30	AEFI – Definition, classification – Management – AEFI surveillance system	

Day 2:

Time	Topic	Responsible

8:30 - 8:40	RECAP	Participants
8:40 - 9:30	Group work exercise on AEFI and plenary	Participants
9:30 – 10:30	Advocacy and Communication	
10:30 - 10:50	Tea break	
10:50 - 12:30	Communication group exercise	
12:30 – 1:30	**Lunch**	
1:30 - 2:30	Monitoring, evaluation and supportive supervision of PCV introduction	
	Practical exercise on HMIS forms	
2:30 – 3:00	Frequently asked questions and discussion	Woreda coordinator
3:00 - 4:00	Planning next level training – Fixing dates of next level training – Preparing standard presentation – Planning participants, number of trainers, and number of concurrent or sequential sessions – Budget break down	
4:00 – 4:20	**Tea break**	
4:20 – 5:00	Planning	
5:00 - 5:30	General discussion	
5:30 - 5:45	Closing	

Annex 13: Agenda for HEWs Training, 2011
Health Center Level

Time	*Activities / Topic*	Responsible
8:30 - 9:00	Registration	
9:00 – 9.10	Objectives and expected outcomes	supervisor
9:10 – 9:40	Pre test	Organizers
9:40 – 10:30	Pneumococcal disease – Transmission, protection, prevention and treatment – Diagnosis and treatment	Supervisor
10:30 – 10:45	**Tea break**	Organizers
10:45 – 11:45	Pneumococcal Vaccine – Vaccine formulation – Vaccination schedule – Vaccine storage and estimation – Preparation and administration – Waste disposal and contraindication	Supervisor
11:45-12:30	Demonstration – Vaccine (VVM, discard after 6 hours label, labeling time of opening), – AD syringe, safety box,	Participants
12:30 – 2:00	**Lunch**	Individually
1:30 - 2:15	Communication ○ Interpersonal communication ○ Key messages on PCV	Supervisor
2:00 – 2:30	Monitoring – Recording and reporting tools – Recording vaccination doses	Supervisor
2:30 – 4:0	AEFI	Supervisor
4:00 – 4:15	**Tea break**	
4:15 – 5:00	Frequently asked questions	Participants
5:00 - 5:30	General discussion	Participants