ADDIS ABABA UNIVERSITY COLLEGE OF BUSINESS AND ECONOMICS

SCHOOL OF COMMERCE

DEPARTMENT OF LOGISTICS AND SUPPLY CHAIN MANAGEMENT

ASSESSMENT ON IMMUNIZATION SUPPLY CHAIN MANAGEENT PRACTICE IN PHARMACEUTICAL FUND AND SUPPLY AGENCY (PFSA)

BY

GULILAT TEFERA (ID: GSE/0147/08)

ADVISOR

DR. MATIWOS ENSERMU

A THESIS SUBMITTED TO THE SCHOOL OF GRADUATE STUDIES OF ADDIS ABABA UNIVERSITY COLLEGE OF BUSINESS AND ECONOMICS SCHOOL OF COMMERCE IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTERS OF ART IN LOGISTICS AND SUPPLY CHAIN MANAGEMENT.

September, 2018

Addis Ababa, Ethiopia

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This is to certify that this thesis entitled with "Assessment on immunization supply chain management practice in Pharmaceutical Fund and Supply Agency (PFSA)" is carried out by Gulilat Tefera Eshetie submitted in partial fulfillment of the requirements of the degree of master of art in logistics and supply chain management complies with the regulations of the university and meets the accepted standards with respect to originality and quality.

Approved by Board of Examiners and advisors;

Dr. Matiwos Ensermu _____ _____

(Adviser) Signature Date

Dr. Tariku Jebena _____ _____

(Internal Examiner) Signature Date

Dr. Baynesagn Asfaw _____ _____

(External Examiner) Signature Date

DECLARATION

I, Gulilat Tefera, the under signed, declare that this thesis entitled “Assessment on immunization supply chain management practice in Pharmaceutical Fund and Supply Agency (PFSA)” is my original work and to the best of my knowledge has never been presented in any other university or college for the award of degree in any other university, that all the sources of material used for the thesis have been duly acknowledged.

Declared by:-

Gulilat Tefera

Signature: _____

Date: _____

STATEMENT OF CERTIFICATION

This thesis, entitled “Assessment on immunization supply chain management practice in Pharmaceutical Fund and Supply Agency (PFSA)” is carried by Gulilat Tefera Eshetie so as to obtain his second degree from Addis Ababa University School of Commerce. He conducted his original thesis under my guidance and supervision. I certify that, the study is his own original work and suitable for submission of the award of MA in Logistics and supply chain Management.

Advisor:

Dr. Matiwos Ensermu

Signature: _____

Date: _____

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ACRONYMS AND ABBREVIATIONS

BCG	Bacille Calmette Guerin
CDC	Center for Disease Prevention and Control
DPT	Diphtheria, Pertussis and Tetanus
EPI	Expanded Program for Immunizations
EVM	Effective Vaccine Management
FEFO	First Expiry First Out
GAVI	Global Alliance for Vaccine and Immunizations
GVAP	Global Vaccine Action Plan
HCMIS	Health Commodity Management Information System
HF	Health Facility
ISCL	Immunizations Supply Chain Logistics System
iSCM	Immunization Supply Chain Management
JSI	John Snow Inc.
MOH	Ministry Health
NHS	National Health Services
NYU	New York University
PATH	Program for Appropriate Technology
PFSA	Pharmaceutical Fund Supply Agency
PLMP	Pharmaceutical Logistics Master Plan
RI	Routine Immunization

UNICEF United Nations Children's Fund

USAID United States Agency for International Development

WHO World Health Organization

VVM Vaccine Vial Monitor

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ABSTRACT

Immunization helps save life, protect serious illness and improve quality of life. It is recognized as one of the most cost effective public health interventions available around the globe. However, the success of this program is heavily dependent on strong immunization supply chain practice. Proper immunization supply chain management ensures availing potent and live vaccines to the community. Ethiopia launched the EPI program since in 1980`s with six traditional antigens. FMOH was also responsible to manage the iSC activities until 2014. Following the national EVM assessment in 2013, FMOH decided to transfer the responsibility of managing iSC to PFSA, aiming to address the existing supply chain bottlenecks identified from the assessment. This research is conducted to assess the immunization supply chain practice following the vaccine transition to PFSA. A descriptive approach was employed to assess the immunization supply chain management, highlighting the storage, handling and distribution components at central PFSA and selected hubs. Census method was used to collect data from key respondents. Interview guides and observation check list was used to collect data for quantitative and qualitative analysis. It was found that; the available storage space at central level is inadequate accompanied with limited maintenance protocol. Temperature monitoring practice during transportation of vaccines was also unsatisfactory. Bundling practice was found to be good, but the knowledge of staffs on basic immunization supply chain attributes is partial. In conclusion, the immunization supply chain practice in PFSA is not well established as per the GAVI`s standard for immunization supply chain fundamentals. Therefore, FMOH and involved stake holders need to capacitate the agency to reach the intended level of quality service.

***Key words**; Immunization, immunization supply chain management, vaccine*

CHAPTER ONE

Introduction

Infectious diseases are increasing due to overcrowding, especially in the third world country and poorer regions of the globe. To combat this infectious disease expanded program for immunization is being on implementation under the global community (Andrea, 2014).

Vaccines are remarkable biological products; it protects the community from disease if handled properly otherwise it can harm instead. According to center for disease control and prevention (CDC) report, vaccines prevent an estimated two to three million death per a year in the global community (CDC, 2015). Vaccines are what the community seeks when a new disease appears. Relative to their great benefit, their cost can be considered minimal. “By keeping deeding and mutilating communicable disease in check vaccine are and will remain essentials to maintaining and expanding health gain. They can be game changing in tackling, future out breaks and epidemics” (CDC, 2015).

Immunization helps save lives, protects serious illness and is recognized as one of the most effective public health intercessions and available today. However, the success of this program depends heavily up on the immunization supply chain management (Steel, 2014)

Strong health supply chains are central to achieving positive health outcomes. They deliver the medicines, vaccines, and other supplies needed to save lives, prevent disease, and empower people to live healthy lives (CDC, 2015). Immunization supply chains (iSC) form a unique distribution channel due to their dependence on a well-functioning end-to-end cold chain necessary for ensuring vaccine potency to the last mile, and ultimately to every person being immunized (WHO, 2014). Vaccine storage, transport, and handling are therefore more challenging than most other pharmaceutical products (WHO, 2014). Immunization supply chains require supply chain workers to have specialized knowledge and competencies. They require storage facilities to have cold rooms or refrigerators and the power supply and technicians to keep them running. They require transport vehicles that are either refrigerated or able to protect cold boxes from heat extremes. And they require information systems able to track vaccine-

specific data, such as vaccine vial monitor (VVM) status, or cold chain equipment (CCE) temperature excursion (CDC, 2015).

1.1 Background of the study

According to CDC`s (2015) report, the immunization supply chain and logistic (ISCL) and system, was designed in the 1980. Starting from its inception, it has supported the achievement of acceptable vaccination coverage, using coping mechanisms to overcome enduing challenges in vaccine storage, distribution and management (WHO, 2014). A strong vaccine supply chain that improves to immunization in all global alliance for vaccine initiatives (GAVI) eligible countries like Ethiopia, take good ISCL as a backbone for its mission to be achieved (Steel, 2014). In order to provide an adequate supply of effective vaccine to support the immunization program, measure need to be in place to ensure the vaccine are maintained at peak efficiency, ensure they are free from bad shipment and storage. The temperature should be safe as per the standard at all point of the supply chain (from the manufacturer up to the last mile, the service delivery point). Nevertheless, failure to adhere the proper cold chain requirements will reduce vaccine potency, poor protection and even risk on the child health. According to the center for disease control, there a saying “It is better to not vaccinate than to administer vaccine that has been mishandled” (CDC, 2015).

Ethiopia, together with the global community launched EPI program since in 1980’s with six traditional antigens. In order to adopt an end to end supply chain of this program, the Ethiopian federal ministry of healthy envisioned the need for proper supply chain of vaccine together with the inception of pharmaceutical logistics master plan (PLMP) in 2007. In 2014, federal minister of health agreed to begin the formal transfer of responsibility for management of vaccine and cold chain to the pharmaceutical fund and supply Agency (PFSA) (PFSA, 2014). On top of this, PFSA was capacitated with twenty refrigerated vehicles and simplified the distribution system from the complex former vertical system (which was center- region-zone- woreda-facility) to a far simpler and short cut of only three and four tier system; PFSA center- PFSA hub – Woreda/health facility (PFSA, 2014).

1.2 Statement of the Problem

Failure to store and handle vaccine properly can reduce vaccine potency resulting in failure in immune responses in children being vaccinated (CDC, 2014). If potency is lost through heat exposure or extensive freeze, the vaccine's appearance will not change without performing a laboratory test, it is not possible to know whether a vaccine has lost its potency or not. As vaccine become ineffective and lack its potency, clients will lose confidence in vaccines. Storage and handling errors can also cost out a countless loss in finance (CDC, 2014).

Vaccines are highly thermo- sensitive biological substance which have a fixed shelf life and lose viability over time. This loss of viability is irreversible and will be accelerated if proper storage and temperature conditions are not maintained. A vaccine vial must remain between 2 and 8 degrees Celsius throughout the entire cold chain system. When it is transported, stored in a refrigerator and when used at immunization sessions (CDC, 2014).

Over stock of vaccine in cold storage and poor shelves arrangement will also lead to inadequate air flow, which can result in risks of increased exposure to heat. In addition, over stocked or poorly stored vaccine can hinder the practice of near expiry first out (FEFO) principle of logistics management. This will in turn result in loss of vaccines (Village Reach, 2014).

According to WHO`s (2014) report, introduction of new vaccine to African countries has also increased storage requirement escalating the existing storage problem.
Regarding personnel's engagement on the immunization supply chain logistics in all GAVI eligible countries, untrained health workers are performing the task (Steele, 2014).

Even though regions scored high immunization coverage rate, there are still a number of out breaks, some of which could be prevented by better vaccine management practices (PATH et al., 2011)

DPT3 coverage of Ethiopia (a back bone indicator for EPI performance) from 2004-2009 E.C was reported poor and stagnant which was 66 to 69 percent only (WHO, 2010). Frequent measles outbreak was reported in some regions of the country even in 2015 (WHO and UNICEF, 2010). Therefore, as PFSA is new for vaccine management, this study tries to assess the practice of immunization supply chain management in line with the WHO standard requirement.

1.3 Research questions

1. How is the storage practice at central and PFSA hubs?
2. How adequate is the positive and negative storage space for storing vaccines at central and PFSA hubs?
3. What is the practice of vaccine transportation?
4. How is the skill and knowledge of staffs engaged on immunization supply chain management?
5. What are the practices of temperature monitoring system?
6. How is bundling practice performed?

1.4 Objectives of the study

1.4.1 General Objective

- The general objective of the study is to assess the immunization supply chain management practice at central PFSA and cluster hubs

1.4.2 Specific objectives

- Assess the storage practice of vaccines at central PFSA and Cluster hubs
- Evaluate the positive and negative temperature storage capacity at central PFSA and cluster Hubs
- Assess the transportation means and adequacy of fleet for distribution.
- Assess the knowledge and skill of staffs engaged on immunization supply chain management practice.
- Assess the temperature monitoring practice during storage and transportation of vaccines from center to hub and from hub to woreda/health facility.
- Assess whether bundling practice is in place while vaccines are distributed to the lower level.

1.5 Significance of the study

Vaccines are important biological preparations which can protect vaccine preventable disease if and only if properly handled, stored and transported from the point of origin to the point of administration. If vaccines lose its potency due to poor management, it will not be effective or

otherwise can harm instead (CDC, 2015). Following the vaccine transition in 2014, PFSA became the responsible agent for storing and distribution vaccines to the service delivery level (PFSA, 2014). As a new job for the agency, this study is therefore a one step forward in assessing the immunization supply chain practice at central and hub level. The study identified important vaccine management related gaps in line with its storage, distribution and transportation at central and cluster hubs. The findings were also used to construct workable recommendations for future improvement. The recommendations are supposed to be helpful for the agency and relevant stake holders to strengthen the immunization supply chain activities at all level.

The findings have the following practical benefits

- ✓ FMOH, PFSA and relevant stake holders will see how the immunization supply chain practice is implemented at central and cluster PFSA hubs
- ✓ Stake holders involved on this will take the finding to address the gaps on immunization supply chain management (iSCM)
- ✓ It will help interested researchers to move forward based on the initial finding from this study.

PFSA is planning to develop five years' strategic plan on immunization supply chain activities (PFSA, 2014). Therefore, the study finding will help to identify basic wick links of the supply chain in line with the storage, temperature monitoring and transportation of vaccines. The study findings will also help stakeholders to consider the different limitations of the exiting transportation by refrigerated vehicles. It can be used as an input while planning for procurement of additional refrigerated vehicles.

Furthermore, this research can be used as a reference material for students and researchers interested to study on the subject area.

1.6 Scope of the study

There are many activities which affect the immunization supply chain practice, which includes the vaccine forecasting, inventory management and procurement. This study mainly addressed assessing the storage and distribution practice at central PFSA and at the six cluster hubs. The storage, handling and transportation of vaccines were assessed using a structured questionnaire

and standard WHO effective vaccine management checklist. On this study, the procurement and supply planning is not addressed due to non-involvement by the Agency.

1.7 Limitations of the study

This study focused on the immunization supply chain practices mainly the storage, handling and transportation of vaccines from center to hub and from hubs to service delivery level. More meaningful results would have been produced if the scope of the study was extended to the whole attributes of GAVI`s Immunization supply chain fundamentals. Definition of key terms and concepts

- **Vaccines** are biological preparations that contain an agent that resembles the disease causing microorganisms and often made from a weakened or killed forms of the microbe, its toxin or one of its surface proteins in order to improve or stimulate body`s own immune system
- **Immunization** is the process whereby a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine
- **Immunization supply chain**: is a system used to ensure effective vaccine storage, handling, distribution and stock management. Also include rigorous temperature control in the cold chain.
- **Bundling** is the practice of integrating the supply of vaccines along with its consumables (diluents, injection and safety materials)
- **Vaccine Vial Monitor (VVM) -** is a label containing a heat-sensitive material which is placed on a vaccine vial to register cumulative heat exposure over time

1.8 Organization of the study

This study is organized into five chapters. The first chapter presents information about the introductory part including background of the study, statement of the problem, research questions, objective of the study, significance of the study, scope of the study, limitations of the study, and definition of terms.

Chapter two includes review of related literatures that are both conceptual and theoretical literature and empirical literature on immunization supply chain management

The third chapter focuses on research design and methodology of the study. It describes the type and design of the research to be persuade, concepts adapted from previous studies, detail description of participants/sample/ of the study, data sources, data collection tools and procedures, methods of data analysis and the like.

Chapter four addresses the results and discussions about the research. Here, the results/findings of the study are summarized and interpretation as well as discussion with the use of related literature review is explained. Finally, the fifth chapter consists of summary, conclusion and recommendation of the study.

CHAPTER TWO

2. Literature review

In the literature, the theoretical perspective will have an explanation on the basic components of the immunization supply chain practices.

The review also discusses about the general practices on immunization supply chain in line with the basic supply chain fundamentals. Country`s experience both from the global and African perspective will also be addressed.

2.1 Theoretical Perspective

2.1.1 Immunization Supply Chain

The immunization supply chain comprises all personnel, the system, cold chain equipment and all activities performed to ensure the efficiency and effectiveness of vaccines to be delivered from the point of origin to the point of administration (Judith, Roger and James, 2011).

Factors that are affecting the immunization supply chain management such as the advocacy on the decade of vaccine, the introduction of voluminous and costly vaccines and lower immunization coverage in many developing countries have led to a new emphasis on strengthening global and in-country immunization supply chains for vaccines and related product (JSI, 2014).

2.1.1.1 Role of immunization supply chain in the immunization practice

Immunization supply chain management practice plays a vital role in the immunization service. As it is a critical element, strengthening of the system is necessary to provide better immunization services in Ethiopia. It helps ensure regular and smooth flow of vaccines and related supplies from the higher supply chain level to the service delivery points (PFSA, 2014)

According to the report from WHO (2014) the immunization supply chain management, which was designed in the 1980s, have supported the achievement of acceptable vaccination coverage, using variety of systems and mechanisms to overcome persistent challenges in vaccine storage, distribution activities. Given efforts undertaken to improve the overall supply chain system, the new vaccines on pipeline and campaign operations to boost the routine activity will increase the storage space constraint (WHO, 2014)

WHO (2014) sates that "a widening variety of new vaccines and immunization schedules, a diversity of service delivery strategies, an expanding target population, increased cold-chain infrastructure requirements and insufficient funding, are just a few of the new realities that will further stress ISC systems, which were initially designed to manage fewer, less expensive and less bulky vaccines and related supplies". With the current system, it is difficult to cope the existing iSCM challenges unless countries give due attention for this area. If not it will result in stock-outs, potential administration of ineffective vaccines, increase avoidable wastage and inadequate cold-chain capacity. These inefficiencies not only affect the immunization coverage, but potentially hamper the return on health investment (WHO, 2014).

2.1.1.2 Immunization Supply chain key functions

Effective Vaccine Management (EVM), launched by the World Health Organization (WHO) and UNICEF in 2010, is a tool used to assess the process of immunization supply chain management using a detailed WHO criterion (WHO, 2014)

EVM measures a wide spectrum of key immunization supply chain activities, including the following

1) **Temperature control**

*"*Keeping vaccines at the recommended temperature is called **maintaining the cold chain**. The cold chain begins at the manufacturer, extends to the distributor, and continues in the provider site until the vaccine is administered" (WHO, 2012.) Proper vaccine temperature must be maintained during transit and at every link in the chain to ensure its viability.

Vaccine cold chain failure occurs when there is a break in any link of the chain. Cold chain failure may occur due to a power failure, staff error, equipment failure, etc. Preventing vaccine cold chain failure requires: properly functioning equipment, appropriately trained staff, clearly written procedures, and easily accessible emergency operating protocols (WHO, 2014).

Temperature monitoring is a critical part of good storage and handling practice and it is necessary to undergo periodic calibration testing. Testing should be performed every 1 to 2 years from the last testing date or according to the manufacturer's suggested timeline. CDC (2014) recommends that testing meets standards defined in the *Vaccine Storage and Handling Toolkit*. If

calibration testing indicates that the temperature monitoring device is no longer accurate, it should be replaced.

All vaccines and their diluents must be stored and distributed within a cold-chain system that maintains, at all times, the WHO-recommended temperatures ranges for all types of vaccines (WHO, 2014)

Vaccine Sensitivities

a. *To freezing:*

That is, vaccines such as Hepatitis B, DPT and TT should never be kept in subzero temperatures and if

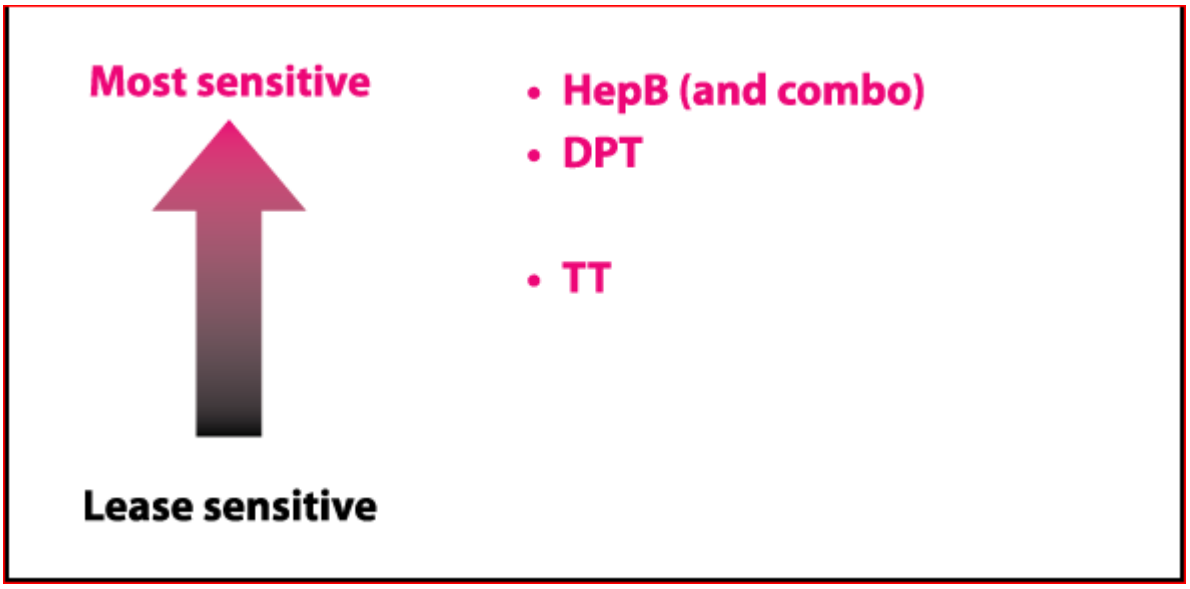

Figure 2. 1 *Sensitivity of vaccines for freezing (UNOPS, n.d)*

frozen they will be permanently damaged. Whereas measles and OPV can be stored if required, in freezing / very cold conditions.

b. *To elevated temperatures*

Vaccines such as BCG, OPV and measles should not be left out in high temperatures for long.

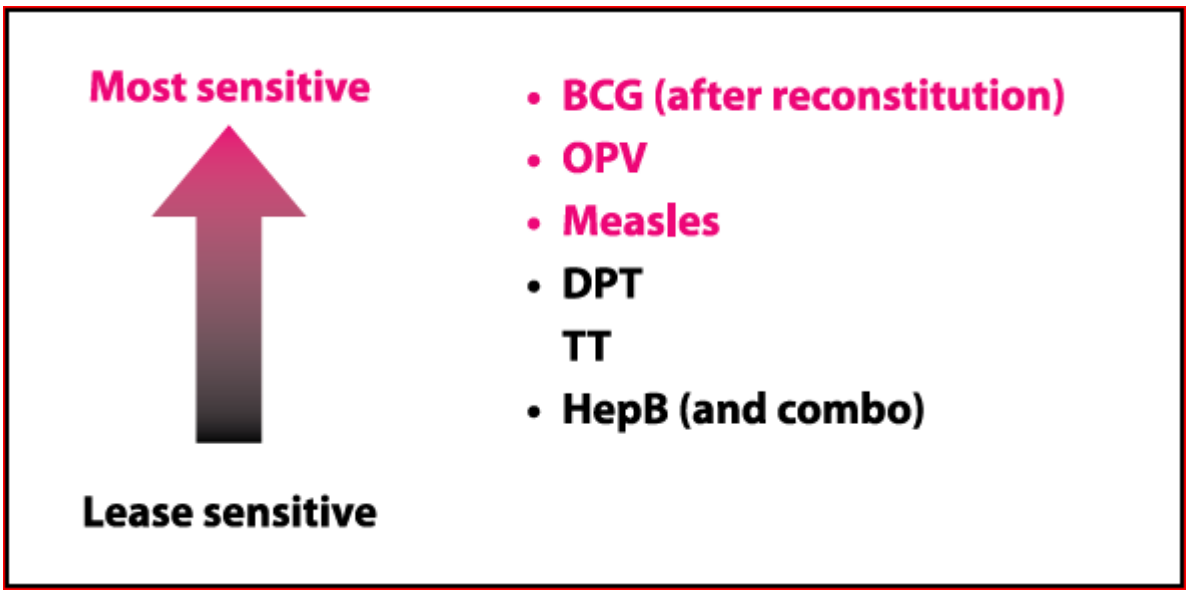

Figure 2. 2 *Sensitivity of vaccines for high temperature (UNOPS, n.d)*

Following re constitution BCG & measles vaccination should be used within 4 hours.

c. To light;

Vaccine sensitive for light are BCG and measles and such vaccines are packaged in amber colored vials (UNOPS, n.d.).

2) **Storage of vaccines**

Appropriate storage and handling of vaccines is one of an important issue to be considered in the immunization supply chain management practice, which can play a vital role in decreasing vaccine preventable disease. Exposure of vaccines to temperatures outside the recommended ranges can decrease their potency and reduce the effectiveness and protection they provide. Storage and handling errors can also result in tremendous amount of money lost due to vaccine wastage and revaccination. Mishandling vaccines can also result in the loss of patient confidence when repeat doses are required due to loose of potency on the antigens. Therefore, vaccine management, including proper storage and handling procedures, is the basis on which good immunization practices are built (WHO, 2014).

Vaccines must be stored properly from the time they are manufactured until they are administered. Assuring vaccine quality and maintaining the cold chain is a shared responsibility among manufacturers, distributors, public health staff, and health-care providers. A proper cold chain is a temperature-controlled supply chain that includes all equipment and procedures used

in the transport and storage and handling of vaccines from the time of manufacture to administration of the vaccine. In order to properly monitor the storage condition of vaccines, the temperature monitoring form should be manually completed twice a day by the health workers recording cold chain equipment temperature (Village Reach, 2014). By implementing best storage and handling practices, providers can ensure that patients will get the full benefit of vaccines they receive (WHO, 2014).

For proper handling and storage of vaccines, there shall be appropriate storage space for storage of vaccines. The EPI schedule, including the newly introduced vaccines (Rota and PCV) requires a total of about 300cm3 per fully immunized child. However, as cold chain requiring pharmaceuticals like oxytocin and rapid diagnostics testing (RDT) test volume is increasing, the storage space assumption shall also consider all this and additional storage for immunization campaign operations. In addition to a cold chain, adequate dry storage is also needed for the bundled safe injection supplies and vaccine consumables such as diluents (UNICEF, 2009).

3) **Distribution**

The transport of vaccine between each level in the supply chain need to be effective, including the correct use of passive containers such as cold boxes, packing practices with coolant packs such as conditioned ice-packs or cool water packs, temperature monitoring during transportation and maintaining transport contingency plans (WHO, 2014)

Conditioning of ice-packs: Icepacks come out of the freezer at a temperature of about -20ºC. They need to be kept at room temperature for a period of time to allow the ice at the core of the icepack to rise to 0ºC. This process is called 'conditioning'. The standard advice has been that an icepack is adequately 'conditioned' as soon as beads of water cover its surface. Experiments have shown that this is not always the case and that cold-sensitive vaccines – particularly Hepatitis B - can still freeze inside the cold box even when icepacks have apparently been conditioned correctly (WHO, 2014)

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

• Leave a 5 cm space all round each icepack.

• Lay out icepacks, preferably in single rows but never in more than two rows.

• Wait until there is a small amount of liquid water inside the icepacks. This will take up to one hour at +20ºC and rather less at higher temperatures. Shake one of the icepacks every few minutes.

The ice is conditioned as soon as it begins to move about slightly inside its container (UNOPS, n.d.).

Arrangement for transport is one of the most important components of immunization logistics management. Apart from ensuring the arrangement of the vehicle, important facilities for distribution of vaccines like adequate quantity of ice packs, trained driver and delivery personnel and the necessary logistics for the vehicle need to be maintained. Ensure loading and unloading of vaccines is done during cooler times of day (early morning, evening) and the van is not left in the sun for long. Ensure somebody is there at the place of unloading so that vaccines are immediately transferred after carrying out transportation. There should be planned and fixed days for collection, often cyclical and once monthly, from the higher stores and not erratic on episodes of stock outs and emergencies. This would only be possible when there is proper logistics planning and coordination between the supplying and receiving stores. Apart from collection, proper arrangement is also required for distribution of vaccine and logistics. The terrain and difficulties of faraway outreach sites should particularly keep in mind while making the arrangement. The further distribution could be outsourced to local volunteers or organizations and is called “alternate vaccine delivery”. The routes, persons responsible, the timings and the logistic materials and quantities need to be meticulously planned (UNOPS, n.d.).

4) **Vaccine handling**

All recommended policies for vaccine management need to be adopted and implemented on the countries immunization supply chain practice, including the use of vaccine vial monitors (VVMs), the shake-test, the multi-dose vial policy (MDVP), the use of diluents and the monitoring of vaccine wastage rates (WHO, 2014).

Vaccine vial monitors: A VVM is a label containing a heat-sensitive material which is placed on a vaccine vial to register cumulative heat exposure over time. The combined effects of time and temperature cause the inner square of the VVM to darken gradually and irreversibly. Before opening a vial, check the status of the VVM. The VVM does not directly measure vaccine potency but it gives information about the main factor that affects potency: heat exposure over a

period of time. The VVM does not, however, measure exposure to freezing that contributes to the degradation of freeze sensitive vaccines. VVM markers are placed on the labels of liquid vaccines (OPV, DPT, HepB) and on the caps of vaccines which need reconstitution (BCG, measles). On opening the caps of the dry vaccines, the VVM becomes irrelevant. However, it is expected that the vaccines are reconstituted (mixed) immediately with the same diluents (mixing solvent) supplied by the supplier and then used within 4 hours. After 4hrs the reconstituted vaccines need to be discarded (UNOPS, n.d.).

Usable Stages	Unusable Stages
	
Reading the Stages of the VVM The inner square s lighter than the outer circle. If the expiry date has not been passed: Use the vaccine	**Discard Point** The color of the inner square matches that of the outer circle: ***DO NOT*** use the vaccine. If the color of the inner square is darker than the outer circle, DO NOT use the vaccine.

Figure 2. 3 *Reading the stage of VVM (UNOPS, n.d.)*

Freezing of vaccines and shake tests: This test is to be undertaken for vaccines which are suspected to have been frozen and not for vaccines which are frozen and can be seen as such. Frozen vaccine must be immediately discarded (UNOPS, n.d.).

2.1.2 Knowledge and practice on ISCM

One of the key supply chain component as per GAVI`s immunization supply chain management is the people and practice aspect. This involves establishing human resource policies, education programs, and training and supervision systems to ensure that leaders and professionals with strong supply chain management capabilities are in place to manage distribution and supply chain performance (GAVI, 2014).

All personnel who handle deliver or receive vaccine shipments and anyone who has access to the unit(s) where vaccines are stored need to have the proper knowledge on vaccines. Vaccine storage and handling training should be provided to all new personnel who handle or administer vaccines, including temporary staff. Continuing education for staff is essential when new vaccines are stocked and when there are any changes to the storage and handling guidelines for a

particular vaccine. It is mandatory to familiarize the storage and handling of vaccines for all institutions engaged on immunization supply chain activities (GAVI, 2014).

2.2 Empirical perspective

Around 1.5 million children in the world die every year because of vaccine preventable disease. Many children do not receive the basic, cheap, life protecting vaccines. Other children receive some doses, but dysfunctional in the health care system or a reliable dose is not given (WHO, 2014). There were an estimated 5.2 million deaths of children between one and five years old, of which 29 percent could be avoided with vaccination (NYU, 2015).

Global Alliance for Vaccine Program (GVAP) states "At this mid-way through the decade of vaccines, the current process and coping mechanisms are not adequately keeping pace with the changing vaccine landscape" (GAVI, 2014). It suggests, being able to continue to serve the community, it is essential to analyze the immunization programs supply chains challenges like extensive vaccine wastage, poor storage, transportation pattern and the like (GAVI, 2014).

Most of GAVI eligible countries reported a vaccine wastage rate in excess of WHO's recommendation and 20 percent states of Nigeria had experienced vaccine stock out. In this same report, around 2.8 million vaccine doses are lost in five countries due to cold chain failure and less than 10 percent of countries meet WHO recommendation for effective vaccine management practices. The report also dictates, 5 percent of GAVI eligible countries are underperforming on ISCL and less than 25 percent of countries are operating at even a minimum standard on the criteria of maintenance, stock management and distribution. Furthermore, only 29 percent of the countries meet a minimum standard for temperature control (WHO, 2014). Vaccine wastage assessment done in India shows, wastage of all level of the supply chain for a six-month period reflects that maximum wastage occur at the session site (BCG vaccine has the maximum wastage of 61 percent) (UNICEF, 2010).

A study conducted in federal republic of Nigeria shows, vaccine supply particularly for DPT and yellow fever in the year 2012 was inconsistent due to reduced or limited global production. According to this study`s finding, barriers of immunization service were identified as vaccine stock out and cold chain equipment failure. The 2012 vaccine audit for routine immunization

program of Nigeria shows, persistent vaccine shortage at health facility was the major impact on the immunization coverage (Anonymous, n.d.). WHO also reported that, in each year on average of 18 and 20 percent of GAVI countries report district level stock outs of DTP and BCG respectively. It has also indicated that more than 20 percent of wastage rates for DTP were above the expected rate (WHO, n.d.).

An assessment done on immunization service in Tanzania shows vaccine stock out was one of the reasons for low coverage and high dropout rate. The cold chain evaluation shows, 30 percent of the health centers visited had vaccine shortage due to poor supply chain infrastructure (MOH, 2000).

When multiple vaccines become available and are added to the existing vaccine regimens, the storage and delivering capacity in many countries is expected to quickly compromised (Judith etal., 2011). WHO reported that a new vaccine introduction by 2008 in Turkey increased the storage requirement by twenty fold (WHO, 2014).

A case study done in Nairobi`s cold chain supply logistics on the safety of vaccine shows up to 52 percent of respondents conformed there was poor validation and qualification of storage facility and monitoring device. There was no different storage equipment for different vaccine up to 41 percent of the organizations and hence run a risk of cross contamination and temperature excursions during storage which has compromised the quality of vaccine. The research confirmed that validate systems with respect to calibration of storage facility temperature probes and sensors and thermometer were generally poor along the supply chain with only 34 percent having satisfactory practice (Monicah, Christopher and Kepha, 2015).

According to a study conducted by National Health Service (NHS), a routine infection control audit in UK had showed that childhood vaccine had been stored incorrectly which had resulted in an extensive vaccine recall. A two-year retrospective audit also showed out of 96 practices, 40 percent of vaccine had been stored outside the recommended temperature (NHS, 2010). Cold chain and vaccine management assessment for animal vaccine program in Indonesia showed approximately half the refrigerators are unsuitable for vaccine storage. Those being used at the time of the study were with some modification were generally in poor condition the temperature was not being monitored; no one knows if any refrigerator temperature goes outside the 2-8-degree celsius range recommended for vaccine. The study also indicated vaccines were mixed

with other items including expired and used vaccine vials (USAID, 2011). Another study in Tanzania also showed most parameters of storage conditions were not meet by the facilities. No health care facility visited was found maintaining recommended temperature range of vaccine freezer. Fridge /freezer tag monitor in refrigerator was present on average only in ten percent of all visited health facilities specifically those tags found were in the regional vaccine store. Ten percent of the surveyed health facilities were found using domestic refrigerator for vaccine storage which was bad storage practice and is not recommended by WHO (Makuru, 2012).

Regarding distribution and transportation practices in line with the WHO's set nine criteria, GAVI eligible countries performance was very poor in vaccine distribution (WHO, n.d.). The organization also noted that twenty-five percent of all vaccine products reach destination in a degraded state. According to medicines and health care product regulatory authority (MHRA) of the United Kingdom, thirty-two percent of all critical and major deficiencies recorded were related poor monitoring of storage and transportation temperature. The study in Nairobi country concluded there was no procedure in place to verify actual temperature of cold chain medicines before taking delivering or dispatch to retail facility and transport of vaccine (Monicah, 2015)

Makuru (2012) stated that the distribution of vaccines from the region to the district vaccine storage was not as per GAVI`s recommendations. Instead of the region vaccine storage level to distribute the vaccine to district level; the district store levels are collecting the vaccine from the regional store. This in turn has affected the proper transportation of vaccines due to lack of adequate transportation means at district level, resulting in shortage of vaccines at the service delivery point. Logistics and supply chain infrastructure issues also play a role in poor routine immunization (RI) performance. In the effective vaccine management (EVM) assessment, 81 percent of local government area (LGAs) and 54 percent of health facility (HFs) of GAVI`s country did not have vehicles for vaccine distribution. The same assessment showed 96 percent of HFs visited had no refrigerators for vaccine storage, which severely impacts vaccine inventory at HF level (Anonymous, n.d.).

In Nairobi, it was confirmed that, up to 76 percent of the firms do not have a fleet system that helps manage the distribution of vaccines (Monicah etal., 2015). Makuru (2012) indicated that the main cause of stock out at health facilities was due to delays in delivering vaccines from

district stores to health facility because of shortage or lack of transport means to distribute vaccines from district.

In the developing countries, the credit given for logistics and supply chain is very minimal. In Tanzania, all 100 percent respondents involved in handling vaccine were non pharmaceutical personnel. Only 8 percent know about the temperature range recommended for freezers (Makuru, 2012). The study in Indonesia also shows, animal health personnel do to have updated information about cold chain or vaccine management. They were using frozen cold packs or solid ice cubes for vaccine transport often causing vaccines to freeze which can totally damage freeze sensitive vaccines. Makuru (2012) also stated, there was no involvement of pharmaceutical personnel in the EPI program.

In lower income countries of Africa, efforts to implement an efficient cold chain supply process are often hampered by poor health delivery systems. Low political commitment, low levels of investment, poorly maintained cold chain, lack of human resource, poor disease surveillance and reporting systems which are key components of the logistics process are some of the bottleneck observed in the system (Monicah etal., 2015).

According to report from world health organization the average inventory holding point of Ethiopia, which is conducted at five supply chain level, was speculated to increase the wastage rate (WHO, 2014).

WHO reported that in Ethiopia 30 percent of cold chain equipment are nonfunctional due to lack of maintenance (WHO, 2014).

2.3 Summary of Identified Literature gap

The empirical reviews clearly dictate that the immunization supply chain is a back bone for well-functioning and efficient immunization program. Due to the peculiar nature of vaccines, there must be a resilient, agile and efficient supply chain system which can ensure a reliable and predictable supply at all levels of the system. There are few studies conducted on immunization supply chain practice in Africa. A short assessment that was done by USAID on vaccine supply chain in Ethiopia was highlighting only on the impact of information system on improving quality of care (JSI, 2014)

During the course of the article selection stage for the literature review, the search on Google Scholar of the terms ― immunization supply chain management practice in Ethiopia/PFSA or ―vaccine supply chain in Ethiopia/PFSA ―did not deliver any relevant articles to be incorporated to the literature review. Moreover, the effective vaccine management assessment (EVMA) that was done by the ministry of health in 2013 addresses only regional health bureau, zonal health departments and woreda health offices, but not PFSA hubs (FMOH, 2013). Therefore, as PFSA is new for vaccine management, this research was found to play a vital role addressing the immunization practice in the PFSA context.

2.4 Conceptual frame work of the study

The conceptual frame work for this study is developed based on the analysis and concepts from the literature review discussed above. Patrick (2015) states that conceptual framework represents the researcher's synthesis of literature on how to explain a phenomenon. It helps to map out the actions and activities required to address the research gaps identified from the previous researchers on the on the study area. It also helps to connect and correlate different variables of the study (Patrick, 2015). The researcher has assessed the immunization supply chain practice, basically the key operations such as storage, handling, distribution of vaccines and temperature control on the cold chain. The ground of this conceptual frame work is if all of these basic activities are performed well, it will contribute to ensure an effective immunization supply chain, which in turn will result in availing potent vaccine for the end users.

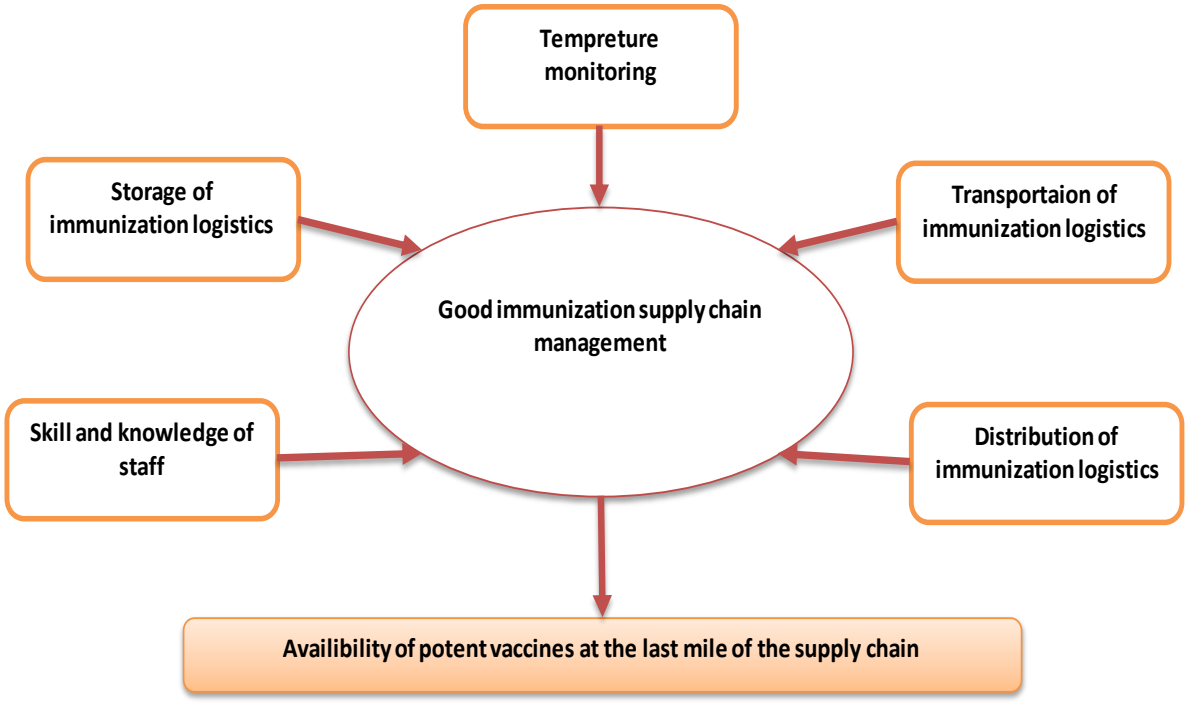

Figure 2. 4 *Conceptual framework of the study developed by the researcher*

CHAPTER THREE

3. Methodology

3.1 Description of the study area

PFSA is an agency established in a geographic base of the country to avail pharmaceuticals for public health facilities. It has a total of 19 hubs at major cities, from which six major hubs are selected to coordinate at a cluster level. This study was conducted at central PFSA and six cluster hubs: Jimma, Bahirdar, Addis Ababa, Hawassa, Diredawa and Mekelle. The study population was thus central PFSA and all PFSA hubs. Staffs involved on immunization supply chain management namely, stock and distribution coordinators, vaccine focal persons, cold room managers, refrigerated truck drivers, vaccine delivery personnel and the CCE maintenance technicians were selected to be the study respondents (PFSA, 2017).

3.2 Research approach

In this study, qualitative and quantitative approaches of doing research was employed. A mixed approach was selected in order to address the weakness and strength of both methods (Kothari, 2004). The quantitative approach was used to generate the data in quantitative form which in turn was subjected to rigorous quantitative analysis. The qualitative approach was used to assess the qualitative component of immunization supply chain management practices. It was also used to analyze attitudes, opinions and behaviors of the respondents subjectively (Kothari, 2004).

3.3 Study Design

A descriptive research design was followed to assess and describe the nature; condition and degree of the present situation of immunization supply chain practice of the agency, mainly the storage and distribution of vaccines. A descriptive design is ideal for studies that will be carried out in a limited geographical scope and hence is logistically easier and simpler to conduct considering the limitations of this study (Kothari, 2004). Furthermore, from the point of view of time, the research was one-time research (cross-sectional).

3.4 Unit of analysis

Unit of analysis indicates the level at which the research was performed and which objects are researched or analyzed. Therefore, in this study, central PFSA and the six cluster hubs were taken as a unit of analysis. All staffs involved on vaccine management were interviewed about their knowledge and practice on vaccine distribution and storage practice. Cold rooms and refrigerated trucks were inspected with WHO checklist for the storage practice and transportation activities. Every cold room manager, vaccine focal, stock and distribution coordinators, cold van drivers and maintenance technicians were pertinent respondents in this study. These individuals were selected because they are the main actors on the vaccine storage, transportation and distribution from center to hub and from hub to health facilities.

3.5 Population of the study

Central PFSA and PFSA hubs (Hawassa, Jimma, Bahirdar, Mekelle, Addis Ababa and Diredawa) were the study populations.

3.6 Sampling Procedure and Sample size determination

The study addressed the six cluster hubs and Central PFSA. A purposive sampling method was used because the six cluster hubs have completed the woreda level vaccine transition and has better experience on vaccine management. This type of sampling technique refers to the process by which a researcher selects a sample basing on the experience or knowledge of the group that is to be sampled (Kothari, 2004). Moreover, all staffs who directly engaged on vaccine management were taken as a respondent in this study. Therefore, from the point of selection of respondents, census study conducted by which a complete enumeration of each unit was assessed (Kothari, 2004)

Central PFSA

- Stock and distribution coordinator=1
- Vaccine focal persons = 2
- Cold room managers 3cold rooms * 2 cold room managers = 6
- Refrigerated truck drivers, 4 refrigerated trucks *1 driver=4
- CCE maintenance technicians= 2
- Warehouse supervisor =3

Cluster hubs

- Stock and distribution coordinator, 6 hubs *1 coordinator =6
- Vaccine focal persons, 6hubs * 1 focal person=6
- Cold room managers 6 hubs * 2 cold room managers =12
- Refrigerated truck drivers 6 hubs * 1 driver =6
- CCE maintenance technicians at Hawassa, Jimma, Mekelle and Bahirdar one technician at hub level 4*1=4
- Vaccine delivery person, each at cluster level 6 hubs * 1 focal person=6

Therefore, the total sample size of respondents was the sum of all staffs engaged on immunization supply chain management at the six cluster hubs and central PFSA, which was 58.

3.7 Data source, types and collection procedure

The study used both primary and secondary data collection methods to achieve its objective. The primary data was collected by using structured questionnaires and standard check list for observation. In addition, secondary data was collected from documents and recordings from the manual and electronic recording tools.

In the questionnaire the supply chain practices were grouped into four constructs that are adapted and modified from the WHO effective vaccine management assessment (EVMA) tool (WHO, 2010). These are staffing training & organizational support, knowledge of staff on vaccine management, distribution and transportation of vaccines and vaccine storage.

The knowledge and practice of staff involved on vaccine management was interviewed with a structured questionnaire adapted and modified from the WHO EVM assessment tool (WHO, 2010). In order to collect data from the respective cluster hubs, EPI logistics focal persons were instructed and assigned to collect the data from their respective cluster hubs. Whereas the central level data was collected by the investigator. In addition, standard check list was developed to assess the storage and distribution practice at central PFSA and the six cluster hubs. The same procedure was followed to collect the data as that of the standard questionnaires.

3.8 Data analysis

In the assessment both qualitative and quantitative data were collected and analyzed according to its type. For the analysis of the quantitative data descriptive statistics supported by SPSS

software version 20 was applied and for qualitative data document analysis was done. The questionnaires and checklists were coded and data entered in to the software for qualitative analysis. Descriptive analysis such as frequency and percentiles were employed to analyze the collected data. Data presentations and interpretations were made using tables in order to display the collected data in a concise and meaningful way.

3.9 Ethical Consideration

During data collection, all respondents were informed regarding the scope, purpose and anticipated outcome following the study. Any person who was not interested to participate on the interview was dropped from the assessment.

3.10 Measurement instrument

3.10.1 Validity

To test validity of the questionnaire, pilot study was conducted on two individuals from central PFSA. They were asked if they are not clear with the questionnaires and the researcher was around to take feedback. The questionnaires were also tested in order to ensure that all items are clear and understandable. This was performed before the main study was conducted.

3.10.2 Reliability

The reliability of data was insured by using the SPSS reliability analysis. With this, the analysis result showed cronbach's alpha coefficient of 0.745. The result showed that the data is reliable as compared to the standard threshold of cronbach's alpha coefficient greater than 0.7. This result indicates that the gathered data are reliable as they have a relatively high internal consistency and can be generalized to reflect opinions of all respondents in the target population.

CHAPTER FOUR

4. Data analysis, Result and Discussion

4.1 Result/Findings of the study

In this part the data that were collected using questionnaires and observation checklist will be presented. The data were found important to assess the immunization supply chain practice at central and selected PFSA hubs. The finding and results are also helpful to forward workable recommendations.

Self-administered questionnaires were used to collect the data from different logistics personnel in charge of managing vaccines at different level. In addition, documents such as manual and electronic recording and reporting tools were reviewed. An observation on vaccine storage warehouses and cold rooms was also conducted. The results are organized as follows.

4.1.1 Response Rate and Demographic characteristics

4.1.1.1 Demographic characteristics

Observing the demographic trend or characteristics of the sample population before starting the data analysis helps to make the analysis more meaningful for the reader. The importance of demographic examination in this research is to describe the characteristics of the sample, like proportion of male and female, profession and educational background, their current position in the agency and work experience of respondents. Knowing this variables is important to see the level of staff's competency to manage immunization supply chain activities at the each levels. Accordingly, these variables are summarized and described in the following table.

Table 4. 1 *Respondent Demographic Information, September, 2018*

Item	Category	Frequency	Valid Percent
Position	Stock and distribution	5	9.6
	Vaccine focal	6	11.5
	Maintainance technician	6	11.5
	Driver	6	11.5
	Warehouse Manager	21	40.4
	Deliverer	8	15.4
	Total	52	100.0
Sex	Male	44	84.6
	Female	8	15.4
	Total	52	100.0
Age	26-35	38	73.1
	36-45	12	23.1
	above 45	2	3.8
	Total	52	100.0
Educational Background	Technical school	4	7.7
	College diploma	29	55.8
	Bachler's degree	17	32.7
	Postgraduate	2	3.8
	Total	52	100.0
Years of experinace in the Agency	less than 1 year	4	7.7
	1-5 years	31	59.6
	6-10 years	16	30.8
	more than 10 years	1	1.9
	Total	52	100.0
Years of experince in the current position	less than 1 year	20	38.5
	1-5 years	23	44.2
	6-10 years	7	13.5
	more than 10 years	2	3.8
	Total	52	100.0

Source: *Survey result exported from SPSS 20, 2018*

From the above table the first item of demographic characteristics is about the current working position of respondents in the agency. With this, most of the respondents 21(40.4 present) were found to be cold room warehouse managers, followed by vaccine deliverers which was 8 (15.4 percent). The total number of vaccine focal person, maintenance technicians and driver was the same, 6 (11.5 percent), 6 (11.5 percent) and 6 (11.5 percent) respectively. The respondent's sex category was dominated by male (84.6 percent). Most of the respondents (73.1 percent) were under the age category between 26 and 35 years.

Regarding educational background, 55.8 percent of the respondents were at educational level of Diploma followed by bachelor's degree and technical school accounting for 32.7 percent and 7.7 percent respectively. Most of the respondents (59.6 percent) have worked for at least 1-5 years in the agency and 44.2 percent of them have also worked on the current position they are entitled.

4.1.1.2 Response Rate and Reliability tests

From a total of 58 questionnaires distributed 52 (89.6 percent) of the questionnaires were filled and returned back to the researcher. This reasonably high response rate was made a reality since the researcher was reminding respondents through phone calls and email to fill and return the questionnaires on time. The high response rate enabled to gather sufficient and representative data to generalize the immunization supply chain practice in PFSA. To check item reliability cronbach's alpha coefficient was calculated to 23 items of the questionnaires and result is 0.74. The test results indicate that items reliability is good.

4.1.2 Storage Practice

In this section of study finding report, the storage practice of vaccines was analyzed using the self-administered structured questionnaire and standard WHO effective vaccine management checklist. With this the level of agreement on the storage practice was assessed as follows. Most of the respondents (57.7 percent) agreed and 21.2 percent of the respondents strongly agreed regarding the adequacy of positive storage space requirement for vaccines. Only 3.8 percent of them were strongly disagreed on the adequacy of available positive storage space. Regarding the negative storage space requirement, 23 (44.2 percent) of respondents disagreed on the adequacy of negative storage space (-15 to -20 degree Celsius) to store vaccine which are recommended to be stored under freezing condition. 15.4 percent of them were neutral for this question. 22 (42.3 percent) and 27 (51.9 percent) of respondents replied "agree" and "strongly agree" when they

were asked if there is temperature monitoring device in the cold rooms respectively. In the same way most of the respondents (50 percent) agreed on the practice of daily temperature monitoring is in place. Regarding the availability of backup generator, 40.4 percent of respondents agreed as generator is functional and available where as 25 percent of they were neutral. On contrary to this, 8 (15.4 percent) and 4 (7.7 percent) of respondents disagreed and strongly disagreed respectively. When study participants were asked if there is contingency plan in case of cold room failure, 23 (44.2 percent) of them disagreed and 30.8 percent of them kept neutral. Respondents were also asked if there is proper CCE maintenance protocol for corrective and curative maintenance, 57.7 percent of them replied "disagree". 57.7 percent of respondents said there was temperature excursion on the cold rooms while vaccines were stored inside. Finally, they were asked for the availability of ware house health and safety clothing and majority (48.1 percent) of respondents strongly disagreed.

The storage practice of 10 cold room warehouses was also assessed by using WHO EVM assessment observational check list. The assessment finding showed, a systematic temperature monitoring study has been carried out within the past 5 years for only 40 percent of the cold rooms. In addition, there was no test calibration conducted in the past 12 months on all of the cold rooms. It was observed that there is a complete set of manual temperature records for each and every cold room, freezer room, vaccine refrigerator and vaccine freezer throughout the review period on 80 percent of cold room warehouses. The random 7-day sample of temperature recorder traces/logger printouts for each cold room and freezer room is agreed with the matching manual temperature records on 60 percent of the cold room warehouses assessed. 40 percent of the cold room warehouses witnessed for temperature records formally reviewed at least once a month in order to identify temperature excursions and their causes. The positive storage capacity at all hubs was found to be 167 percent whereas as the central storage capacity was witnessed to be 32.5 percent of the total requirement. 20 percent of the cold room warehouses have SOP which sets out a contingency plan in the event of equipment failure or other emergency conditions. It was also found that, 70 percent of the warehouses have an emergency contact details posted in the vaccine store. When staffs were asked if they know what to do in case of emergency situations, 80 percent of them were able to answer the correct procedures. The conformance of cold room warehouses for proper loading was checked and 70 percent of them are convenient to load packed vaccines directly in to the refrigerated vehicles. Lastly, it was

assessed if refrigeration units are able to maintain the recommended storage temperature range (+2 to +8oC) and witnessed 90 percent of them were able to maintain the required storage temperature range at the time of inspection.

4.1.3 Distribution and transportation

Respondents' level of agreement on the distribution and transportation activities was assessed and the result is described as follows. They were asked if there is reliable and adequate number of fleet for transportation of vaccines, 24 (46.2 percent) of respondents replied "disagree" and 7 (13.5 percent) respondents replied "strongly disagree" whereas 28.8 percent of them agreed as the available vehicle is adequate for vaccine transportation. They were also asked if refrigerated vehicle is pre cooled prior to loading of vaccines and majority (59.6 percent) of them agreed whereas 19.2 percent of them disagreed. It was found that 27 (51.9 percent) of respondents agreed as there is no temperature monitoring during transportation of vaccines.

Table 4. 2 *level of respondents' agreement on temperature monitoring practice during transportation of vaccines, September, 2018*

		Frequency	percent	Valid percent	Cumulative percent
Valid	Disagree	27	51.9	51.9	51.9
	Neutral	7	13.5	13.5	65.4
	Agree	15	28.8	28.8	94.2
	strongly agree	3	5.8	5.8	100.0
	Total	52	100.0	100.0	

Source: *Survey result exported from SPSS 20, 2018*

Majority (61.5 percent) of respondents were agreed for bundling practice is in place during the distribution of vaccines along with its consumables (syringe and safety box). It was found that refrigerated vehicles would stay on average of 3.8 days on field transporting vaccines.

Qualitative observation result on transportation of vaccine at the respective hubs and central PFSA showed, there are no temperature logger printouts for each and every refrigerated vehicle

while transporting vaccines. Only 10 percent of the refrigerated vehicles are equipped with a self-sustained diesel refrigeration unit which can operates when the vehicle engine is switched off. 90 percent of refrigerated vehicles were equipped with a thermometer recorder which can be read in the driver's cabin and able to maintain the recommended temperature range (2 to 8 degree celsius). It was observed that, none of the refrigerated vehicles are equipped with a thermometer recorder which can produce hard copy output.

4.1.4 Knowledge on vaccine management

The knowledge of staff on vaccine management was assessed using case based multiple choice questions and asking respondents to explain about basic attributes of effective vaccine management. 49 (94.2 percent) of the respondents were able to correctly answer the recommended temperature range for most vaccines storage and transportation (2 to 8 degree celsius). Most (96.2 percent) of respondents were also able to recall those vaccines which are recommended to be stored in a freezer room. 46 (88.6 percent) and 40 (76.9 percent) of respondents were able to bring to their mind about the freeze and light sensitive vaccines respectively.

Respondents were also asked if they are able to explain about shake test, VVM, WHO multi dose policy and ice pack conditioning. 29 percent of them were able to correctly explain what shake test mean and the procedures how to conduct the same. On the other hand, 39 percent of them were able to clarify about VVM stages and interpretations. Steps followed for ice pack conditioning was explained by 30 percent of them. Lastly, they were asked if they are able to explain about WHO multi dose vial policy, it was found that 26 percent of them were able to explain about the policy.

4.1.5 Staff training and organizational support

Respondents were asked if they were trained on different activities of vaccine management, 32 (61.8 percent) of respondents replied “yes” when they were asked if they have been given training on how to conduct shake test. Regarding trainings on correct storage temperatures, storage of diluents and how to arrange vaccines in cold rooms, freezer rooms, refrigerators and freezers, it was found that 69.21 percent of them were trained in the same status. 65.4 percent of them were also trained on vaccines which can be frozen, vaccines which must be frozen,

temperature monitoring practice and ice pack conditioning. 38 (73.1 percent) respondents replied as they were trained on VVM reading.

Table 4. 3 *Response rate of respondents training on VVM reading*

		Frequency	percent	Valid percent	Cumulative percent
Valid	Yes	38	73.1	73.1	73.1
	No	14	26.9	26.9	100.0
	Total	52	100.0	100.0	

Source: *Survey result exported from SPSS 20, 2018*

Regarding organizational support on immunization supply chain management, respondents were asked if they have a written guideline, job aids or SOPs for vaccine management, 36 (69.2 percent) of respondents replied “yes”. They were also asked if they have received any supervisory visit on immunization supply chain management. It was found that 46.2 percent of respondents witnessed for receiving supervisory visit.

4.2 Discussion of the findings

Discussions

In this chapter, detailed discussions are presented regarding the study subject. Results obtained in chapter four are the basis for these discussions and then conclusions and recommendations in and for the way forward in addressing the problem of immunization supply chain management practice in PFSA.

Storage Practice

The study finding from the field observation showed that there is 1126m3 (167 percent) storage space a bit higher than the maximum storage requirement at hub level. However, the central storage capacity both for positive and negative storage requirement is very minimal. The national positive storage capacity is only 99m3 (32.5 percent of the total required volume). The negative storage capacity is also 13.3m3 net which is 62.4 percent from the total requirement. These space constraints can hamper the storage condition of vaccines which can lead for potential damage due to improper storage and congestion. Respondents were also complaining for storage space due to the fact that central stocks are consigned at their cold rooms resulting storage constraints. The building of cold room warehouses was witnessed to be very poor and do not meet the minimum standard of WHO EVM requirement. Some of the warehouses are with poor roofing and the wiring system is prone for fire accident. Regarding storage temperature monitoring practice, 76 percent of respondents agreed as the practice is in place. According to Village Reach (2014) the storage temperature condition of cold rooms must be manually registered twice every day in order to monitor the storage condition of vaccines. Contingency plans in case of cold room failure were found to be unsatisfactory. WHO (2013) recommend that there shall be a strict and written contingency plan in order to be used in case of unexpected equipment failure. On this finding, only 20 percent of the cold room ware houses have SOP for contingency plan.

The cold chain equipment maintenance protocol for both corrective and preventive maintenance is also unsatisfactory. 57.7 percent of respondents disagreed on the availability of proper maintenance protocol. Given a huge amount of cold rooms available at the respective facilities, there is no maintenance workshop and spare parts management is very poor. The assigned cold

chain technicians are not officially recruited for maintenance activities and there was no proper maintenance schedule at each level. WHO (2014) also reported that 30 percent of cold chain equipment in Ethiopia are nonfunctional due to lack of maintenance. The finding complement with the fact that there is frequent temperature excursion as per the 57.7 percent of respondents' witness. A study finding conducted by the NHS (2010) was also found that in UK out of 96 practices, 40 percent of vaccine had been stored outside the recommended temperature. In Tanzania, it was found that no health facilities had stored at the recommended temperature range of vaccine freezers at the time of inspection (Makuru, 2012). According to the observation finding, none of the cold rooms were calibrated for the storage temperature. WHO (2013) recommends that there must be test calibration every 12 months.

Distribution and transportation

According to the response from the respondents, transportation of vaccines is conducted mostly by using refrigerated vehicles and sometime they can also use cold box for less voluminous vaccines. Study participants were asked if the fleet capacity is adequate for pick time distribution, 46.2 percent of them disagreed. This study found better than what was found in Nairobi in which 76 percent of firms do not have a fleet system that helps manage the distribution of vaccines (Monicah etal., 2015). WHO also dictated that, 81 percent of local government area and 54 percent of health facilities of GAVI eligible countries do not have vehicles for vaccine distribution (WHO, n.d). Respondents were also asked if the refrigerated vehicles are pre cooled prior to loading, only 59.6 percent of them replied "agree" whereas WHO recommends vehicle must be pre cooled prior to loading of vaccine (WHO, 2013). Unless vehicles are pre cooled prior to loading, vaccines can easily be damaged by the ambient temperature inside the vehicle. In order to reach the desired temperature range, the vehicle engine shall be turned on for 10 minutes before loading (WHO, 2013).

Regarding temperature monitoring practice during transportation, 51.9 percent of respondents replied "there is no temperature monitoring practice during transportation". Even though the refrigerated vehicles are equipped with temperature reading on the driver`s cabin, no test calibration was done for all of the vehicles. It was also found that none of the refrigerated vehicle equipped with temperature logger print out for temperature monitoring purpose. On the other hand, only 10 percent of the refrigerated vehicles are equipped with self-sustained diesel

refrigeration unit which can operate when the vehicle engine is off. However, the study result showed that vehicles can stay on average of 3.8 days on field with overnight stays. This will potentially jeopardize the quality of vaccines as the temperature excursion is inevitable. The study that was conducted in Nairobi also showed that, there was no procedure in place to verify actual temperature of cold chain medicines before taking delivery or dispatch to retail health facility and transport of vaccines (Monicah etal., 2015). In the study conducted on GAVI eligible countries 25 percent of all vaccines products reach to their destination in a degraded state (WHO, n.d).

Regarding the delivery modality, a study conducted in Tanzania showed instead of the region vaccine storage level to distribute the vaccines to district level, the districts are collecting the vaccine from the regional store. This intern has affected the transportation activities because of inadequate fleet capacity at district level (Makuru, 2012). According to the qualitative observation, the PFSA central store is quarterly delivering vaccine to the regional hubs and the regional hubs in turn are delivering vaccines to districts and health facilities monthly. This in turn has resulted in a better transportation service and potential impact on preventing stock outs at service delivery levels.

Knowledge on vaccine management

According to this study`s finding, most of the respondents (94.2 percent) were able to respond the correct temperature range (+2 to +8 degrees Celsius) of vaccines during storage and transportation. This finding result is a bit higher than the one found in Tanzania in which only 71 percent of the respondents were able to correctly answer the correct temperature range for storage and transportation for majority vaccines (Makuru, 2012). 96.2 percent of them were also able to correctly answer the recommended temperature range for vaccines to be stored in freezer room. This finding was also found to be satisfactory compared to the study`s finding in Tanzania (Makuru, 2012). According to this study, only 8 percent staffs were able to know the correct temperature range recommended for freezers (Makuru, 2012).

According to WHO (2014), all recommended policies for vaccine management need to be adopted and implemented on the countries immunization supply chain practice including the use of vaccine vial monitor (VVMs), the shake test and the multi dose vial policy (MDVP). The

finding of this study showed that, only 29 (55.7 percent) of respondents were able to correctly explain about shake test. Only 39 (75 percent) of them were also able to know about VVM interpretations and its stages. Steps to be followed for ice pack conditioning were explained only by 30 (57.7 percent) of the respondents. Lack of knowledge on ice pack conditioning can result in damage on freeze sensitive vaccines during transportations. In Tanzania, Makuru (2012) staffs were using frozen cold packs or solid ice cubes for vaccine transportation which can totally damage those freeze sensitive vaccines.

Staff training and organizational support

From the interview of respondents, the trend of official training on immunization supply chain activity is very minimal. They are instead getting the information from supervisory visits and from their co-workers. This might be the reason for poor knowledge of staffs regarding immunization supply chain activities. For instance, 61.8 percent of the respondents replied “yes” when they were asked if they were trained on shake test. However, only 29 of them were able to correctly recall the procedures for shake test. The study that was conducted in Tanzania showed 60 percent of respondents interviewed had not attended training on storage, distribution and handling of vaccines within the last three years (Makuru, 2012).

WHO (2013) recommends that, immunization supply chain firms must be equipped with the necessary SOPs, job aids and guidelines on immunization supply chain practices. However, this study found that only 69.2 percent of the facilities were equipped with the necessary SOPs, job aids and guidelines. Supervisory visits were also conducted on only 46.2 percent of them.

CHAPTER FIVE

5. Summary of Findings, Conclusions and recommendations

This chapter gives summary of findings, conclusion and recommendations on immunization supply chain practice in PFSA.

5.1 Summary of findings

According to this study`s finding, the positive storage capacity at hub level is above the total need. The central storage capacity is less than half of the requirement for positive storage requirement. Most of the cold room's temperature is monitored daily and reviewed for corrective actions. There is no temperature mapping study conducted at all levels (both at hub and central level). There was no test calibration conducted in the past 12 months on all of the cold rooms. In addition, only few of the cold rooms warehouse have SOP and contingency plan on how to manage emergency situations in case of equipment failure. Distribution of vaccine is mostly conducted using refrigerated vehicles, but the available trucks are not adequate for the pick time distribution. Most of the respondents explained as there is no temperature monitoring practice during transportation of vaccines. Only three of the refrigerated vehicles are equipped with self-sustained diesel refrigeration unit which can operate when the vehicle engine is off. Bundling practice is practiced during distribution of vaccines. Less than half of the respondents were able to correctly answer and explain about shake test, VVM, WHO multi dose policy and ice pack conditioning. Half of the respondents noted that monitoring and supervisory visit regarding immunization supply chain is not conducted since the vaccine transition is commenced.

5.2 Conclusion

The following conclusions are drawn based on the results of the study

- The result has showed that, there is sufficient vaccine storage space at hub level but the negative and positive storage space requirement at central level is inadequate.
- Temperature monitoring practice on storage is relatively good but there is huge gap on temperature monitoring during transportation. Even though the refrigerated vehicles are equipped with temperature monitoring device, it was not clear how they are managing in case of overnight stop. It was also found that vehicles can stay up to 3.8 days on field resulting temperature excursion which in turn can affect the potency of vaccines.

- The CCE maintenance practice is unsatisfactory. Assigned cold chain technicians are not properly trained and they are not in position to manage the complexity of cold room failures.
- The knowledge of staffs on correct temperature range for vaccines storage and transportation is good. However, knowledge on some of the immunization supply chain attributes like about the shake test and ice pack conditioning is limited. Their knowledge about WHO multi dose vial policy is also partial.
- Supervisory visits on immunization supply chain are limited.
- Bundling practice is appropriately followed.

5.3 Recommendations

The following recommendations are forwarded to address the gaps identified on the immunization supply chain practice

- ❖ There is a need to build additional cold rooms and freezer rooms at central level in order to avert the current storage space constraint.
- ❖ As the available refrigerated trucks are not convenient for distribution of vaccines in case of overnight stops, it is better to use only cold box to transport vaccine to service delivery points.
- ❖ In collaboration with FMOH and involved stake holders, the agency better devise a mechanism of remote temperature monitoring practice during transportation of vaccines.
- ❖ Standard SOP and written contingency plan shall be in place for the case of unprecedented CCE failure.
- ❖ It is better to recruit or assign skilled and experienced CCE maintenance technicians at central and cluster level. In addition, cold room managers must be trained on how to conduct routine preventive maintenance activities.
- ❖ FMOH and responsible stake holders shall help the agency on continuous capacity building activities. The agency shall also develop a standard guideline and training manual to continuously improve the skill and knowledge of staffs involved on immunization supply chain activities.
- ❖ It is valuable to conduct a regular supervisory visit

5.4 Areas for Further Research

Because this study just focused on central and selected PFSA hubs, further research can be carried out to cover the whole hubs to assess the magnitude of the problem.

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7. ANNEXES

Annex I. Data collection tool

Immunization Supply Chain Management Assessment Tool

My name is Gulilat Tefera. I am conducting a study on assessment of immunization supply chain management in PFSA for partial fulfillment of master's degree in logistics and supply chain management in Addis Ababa University, School of commerce. The information that will be collected from this research project will be kept confidential. Taking part in this study, you will contribute towards addressing gaps related with immunization supply chain management, particularly the storage and distribution practice at PFSA context.

If you are willing to participate in the research, you need to understand the questionnaires and in case if you have any question you can contact me with the following address

Mobile: +251-912813822

Email: gulelatmam@gmail.com

Your cooperation and on time response will be highly appreciated.

General Instructions

- There is no need of writing your name.
- Where answer options are available please tick (√) in the appropriate box

Section I. **General Information and Demographic Background of Respondents.**

1. Your position in the Agency
   Stock and distribution coordinator ☐ Vaccine focal ☐ Maintenance technician ☐
   Driver ☐ warehouse manager ☐ Deliverer ☐ Warehouse supervisor ☐
2. Gender: Male ☐ Female ☐
3. Age: 18-25 ☐ 26-35 ☐ 36-45 ☐ 36-45 ☐ above 45 ☐
4. Educational Background: Technical school ☐ College Diploma ☐ Bachelor's Degree ☐ Postgraduate ☐
5. How long have you been working in the Agency? Less than 1 Year ☐ 1-5 years ☐
   6-10 years ☐ more than 10 years ☐
6. Years of experience in the current position? Less than 1 Year ☐ 1-5 years ☐
   6-10 years ☐ More than 10 years ☐

Section II. Vaccine Storage

Identify that best describes your position. (Here you are kindly requested to choose your agreement about your agency's position from the box and indicate your response by putting "√" mark , 1 = strongly disagree, 2= disagree, 3= neutral, 4= agree and 5= strongly agree.

Statement	Strongly disagree	disagree	Neutral	Agree	Strongly agree
There is adequate positive storage space for vaccines					
There is adequate negative storage space for vaccines					
There is temperature monitoring device in the cold/freezer room					
Daily temperature monitoring practice is in place (temperature recorded twice daily)					
There is backup generator in case of power outage					
There is contingency plan in case of cold room failure					
There is proper CCE maintenance structure for corrective and preventive maintenance					
Safety warehouse clothing is in place					

7. What is the total number of birth infant under your catchment? _____
8. What is the total number of Surviving infant under your catchment? _____
9. How much is your cold room in cubic meter (gross volume)? _____
10. How much is your freezer room in cubic meter (gross volume)? _____
11. Does it happen that vaccines in cold room or freezer are not in recommended temperature range during storage? Yes ____ No____ **If yes, go to the next question**

12. If yes, what measure or action you have taken when vaccine in stock storage were found out of recommended temperature range? **Please Mention**

    _____

Section III. Distribution and Transportation of vaccines

Identify that best describes your position. (Here you are kindly requested to choose your agreement about your agency's position from the box and indicate your response by putting "√" mark , 1 = strongly disagree, 2= disagree, 3= neutral, 4= agree and 5= strongly agree.

Statement	Strongly disagree	disagree	Neutral	Agree	Strongly agree
There is adequate number of vehicle for transportation of vaccines					
Refrigerated vehicle pre cold before loading of vaccines					
The temperature of vaccine is always monitored during transportation					
There is bundling practice during distribution of vaccines (integrating vaccine with its consumables)					

13. If you are using refrigerated truck for vaccine distribution, how long would you stay on field transporting vaccines? **(please mention the maximum days of stay**) _____

Section VI. Knowledge of staff on vaccine management

14. What is the recommended temperature range for most vaccine stored and transported in degree Celsius?

a. -5 to +10

b. -2 to -8

c. +2 to +8

d. -15 to -20

e. I don't know

15. Which one is highly freeze sensitive vaccine?

a. BOPV

b. Pentavalent

c. BCG

d. Measles

e. I don't know

16. Which vaccine is highly sensitive for light?

a. IPV

b. Measles

c. TT

d. BOPV

e. I don't know

17. Which vaccine is recommended to be stored in freezer room

a. IPV

b. BOPV

c. Pentavalent

d. TT

e. I don't know

18. Do you know about shake test? **Please explain**

_____

_____

19. What is Vaccine Vial Monitor (VVM)? Please Explain

_____

_____

20. Do you know about WHO multi dose vial policy?Please Explain

_____

_____

21. Do you know about conditioning of ice pack? Please Explain

_____

_____

Section V. staffing training &Organizational Support

Have you taken training on any of the following activities?

S/n	Training on	Yes/No	Remark
1	correct storage temperatures;		
2	vaccines damaged by freezing;		
3	vaccines which can be frozen		
4	vaccines which must be frozen;		
5	VVM reading		
6	shake test		
7	temperature monitoring using the range of available devices		
8	storage of diluents		
9	how to arrange vaccines in cold rooms, freezer rooms, refrigerators and freezers		
10	icepack conditioning		
11	cold box/vaccine carrier packing		

22. Do you have a written guideline, job aids or SOP for vaccine management?

Yes ___ No ___

23. Have you got any supervisory support? Yes ___ No ___
24. If your answer for Q 24 is yes, does the supervision include immunization supply chain management? Yes ___ No ___

Summary Analysis

25. In your own opinion, what do you think are the barriers to efficient storage and distribution system of vaccines?

    ……
    ……
    ……

26. What do you finally recommend to improve or strengthen immunization supply chain practice in PFSA?

    ……
    …

Thank you for your cooperation!

Annex II, VACCINES STORAGE AND HANDLING INDICATOR FORM

AGENCY……NAME OF INVESTIGATOR……DATE……

All vaccines and diluents are stored within WHO-recommended temperature ranges?			
S.N	Activity	Result	Guideline notes for assessor
1.	Has a systematic temperature monitoring study been carried out for the cold rooms within the past 5 years? [Y, N]		
2.	Is there a complete set of manual temperature records for each and every cold room, freezer room, vaccine refrigerator and vaccine freezer throughout the review period? [Y, N]		This question applies all in health facilities with active refrigeration. It does not apply in health facilities where cold boxes or vaccine carriers are used to store vaccine temporarily. Manual records are necessary because this is the only way to be sure that temperatures are checked at least twice a day. 'Complete' means that there should be no missing' record sheets or electronic temperature traces and that the entire review period should be covered for each appliance.
3.	Is there a complete set of temperature recorder traces and/or temperature logger printouts for each and every refrigerated vehicle throughout the review period? [Y,N]		This question only applies in health facilities which use refrigerated vehicles.
4.	Does a random 7-day sample		Select a random 7-day period for each

	of temperature recorder traces/logger printouts for each cold room and freezer room agree with the matching manual temperature records? [Y, N].		appliance (not the same period for each). Check the twice daily temperature records against the corresponding times on the temperature trace. If the record is consistently within 2°C of the trace, this is acceptable. If there are significant discrepancies, especially if the temperature record is uniform and the trace is not, interview staff to establish the reasons.
5.	Are temperature records formally reviewed at least once a month in order to identify temperature excursions and their causes? [Y, N]		Check whether records are reviewed and recorded. 'Excursions' are temperatures below +2°C or above +8°C for cold rooms and vaccine refrigerators, and above -5°C for freezer rooms and vaccine freezers.
6.	Have correct remedial actions been taken? [Y, N, n/a if there are no excursions or breakdowns]		Interview the responsible person. Discuss and evaluate remedial actions taken.
7.	Is there a test calibration record to show that the cold rooms, freezer rooms and refrigerated vehicle (if used) are calibrated every 12 months? [Y,N]		Since calibration is a relatively complex and technical process it should be avoided wherever possible by choosing temperature monitoring devices which retain their calibration for extended periods, or which can be recalibrated automatically - e.g. by replacing a digital sensor. For service delivery level equipment calibration is impractical. However, stem

			thermometers hold their calibration well and Fridge-tags are effectively calibrated for life (2-3 years). Bi-metallic dial thermometers loose calibration quite easily and are now excluded from PQS.
Cold storage, dry storage and transport capacity is sufficient to accommodate all vaccines and supplies needed?			
8.	Is there sufficient storage capacity for icepacks/chilled water packs storage to meet peak demand? [Y, N].		Peak demand' is the maximum weight of icepacks/chilled water packs required in a day.
9.	Is there a satisfactory SOP which sets out a contingency plan in the event of equipment failure or other emergency? [Y, N].		Identify at least two alternative cold storage locations. Inspect them to make sure they are large enough, well-managed, and can maintain correct temperatures.
10.	Are emergency contact details posted in the vaccine store? [Y, N].		Ensure that there is a written agreement with the selected emergency providers. If payment will be required, make sure that this can be funded.
11.	Does staff know what to do in the event of an emergency? [Y, N].		Regularly rehearse the contingency plan with store staff and the emergency providers.
12.	Can packed vaccines be loaded directly into the refrigerated vehicle? [Y, N].		

13.	Do the refrigeration units maintain a temperature of +2°C to +8°C? [Y, N].		
14.	Are vehicles equipped with a self-sustained diesel refrigeration unit which can operate when the vehicle's engine is switched off? [Y, N]		
15.	Are vehicles equipped with a thermometer which can be read in the driver's cab? [Y, N]		
16.	Are vehicles equipped with a temperature recorder which can produce hard copy output? [Y, N]		
17.	Is there an SOP showing how the vehicle(s) should be packed? [Y, N]		
18.	Do drivers have a radio or mobile phone to contact the supplying store and/or the receiving store during transit? [Y, N].		

Adapted from WHOEVM assessment check list (E2, E3 and E7)