Research Article

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Assessment on Vaccine Supply Chain and Logistics Systems in the Case of Ethiopian Pharmaceuticals Supply Agency JIMMA Branch

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Abstract

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 the programs depends heavily upon the immunization supply chain management including storage, transportation, and handling of vaccines in a proper manner. It was, therefore, important to assess the immunization supply chain and logistics practice. The study was conducted at the EPSA Jimma branch. Purposive sampling methods were used because the hub has completed the Woreda level vaccine transition and have a better experience in vaccine management. Moreover, all staffs (7) who directly engage in vaccine management were a respondent in this study. The primary data was collected using structured questionnaires and Standard checklist observation. In addition, secondary data was collected from documents and recordings from the manual and electronic recording tools. Qualitative and quantitative data were collected and analyzed according to their 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. SPSS mean and the standard deviation was used to calculate and show the expert's experience on immunization supply chain practices, and frequency and percentage were considered to present the respective practices. The result showed that there are rooms for improvement to ensure recommended good storage. The branch has sufficient positive (+20C to +80C) storage capacity, but the available negative storage volume only covers 65% of the negative storage capacity needed. Respondents were agreed on bundling practice during the distribution of vaccines, Disagree on Refrigerated vehicle pre cold before loading of vaccines, whereas strongly disagree on the temperature of vaccine is always monitored during transportation and availability of an adequate number of the vehicle for transportation of vaccines for which respondents remained neutral. The study strongly indicates the need to improve vaccine logistics supply chain management practices, especially in vaccine storage and handling and temperature monitoring. EPSA and development partners working on vaccine logistic and supply chain management should have intensified their technical and material support to improve the vaccine management practices.

Keywords: Vaccine logistics and supply chain management.

Introduction

Infectious diseases are on the increase 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 in all of 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 the programs depends heavily up on the immunization supply chain management including storage, transportation and handling of vaccines in a proper manner (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).

Background of the Study

According to CDC`s 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. CDC says "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 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. To improve vaccine management and distribution system, in 2014, federal minister of health agreed to begin the formal transfer of responsibility for management of vaccine and cold chain along with other health commodities to the Ethiopian pharmaceutical supply Agency (EPSA) (EPSA, 2014) where the transition from existing management system was conducted in a phase based approach. For first phase of the transition, Mekelle, Bahir Dar and Jimma EPSA Hubs are selected. Commencing vaccine distribution from these Phase I Hubs to Zones require forecasting of vaccine requirement for the catchment areas the hubs serve, submission of those forecasts using Vaccine Request Forms (VRFs) to EPSA Central/FMOH EPI team, and delivery of vaccines from EPSA Central to the hubs, as per their requests. On top of this, EPSA Jimma was capacitated with 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; EPSA center- EPSA hub –Woreda/health facility (EPSA, 2014).

In line with this, the existing health commodity management and information system (HCMIS) software which EPSA was using it for managing the information system for pharmaceuticals, become one of the important tool for managing the information system and inventory control of vaccines.

Statement of 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 in 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 leads 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, which will in turn result in loss of vaccines (Village Reach, 2014).

According to WHO`s report, introduction of new vaccine to African countries has also increased storage requirement escalating the existing storage problem (WHO, 2014).

Regarding personnel's engagement on the immunization supply chain logistics in all GAVI eligible Countries, generally untrained health workers are performing the task (Steele, 2014).

According to PATH`s report, even though regions scored high im-

munization 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 EPSA is new for vaccine management, this study was assessed the practice of vaccine management in line with the WHO standard.

Research questions

1. How is the storage practice at EPSA Jimma branch?
2. How adequate is the positive and negative storage space for storing vaccines?
3. What is the practice of vaccine transportation to the service delivery point?
4. How is the skill and knowledge of staffs engaged on vaccine management?
5. What are the practices of temperature monitoring system?
6. How is bundling practice performed?

Objectives

General Objective

- To assess the immunization supply chain and logistics practice at EPSA Jimma branch

Specific objectives

- To Assess the storage practice of vaccines at EPSA JimmaTo Evaluate the positive and negative temperature storage capacity at EPSA Jimma
- To Review the transportation means and adequacy of fleet for distribution.
- To assess the knowledge and skill of staffs engaged on immunization supply chain management practice.
- To assess the temperature monitoring practice during storage and transportation of vaccines from center to hub and from hub to Woreda/health facility.
- To assess whether bundling practice is in place while vaccines are distributed to the lower level.

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, EPSA became the responsible agent for storing and distribution vaccines to the service delivery level (EPSA, 2014). As a new job for the agency, this study is therefore a one step forward to assess the immunization supply chain practice at the top level of the supply chain. The study will help to identify important vaccine management related gaps in line with its storage, distribution and transportation at Jimma hub. It will also help put recommendations for its improvement.

The finding will have the following practical benefits

- FMOH, EPSA and relevant stake holders will see how the immunization supply chain practice is implemented
- 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.

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 addresses assessing the storage and distribution practice at EPSA Jimma branch. The storage, handling and transportation of vaccines were assessed using a structured questionnaire and standard WHO effective vaccine management checklist.

Limitations of the study

This study focuses on the immunization supply chain practice mainly the storage, handling and transportation of vaccines from center to hub and from hubs to service delivery level (Woreda and health facilities). Therefore, as the study area is limited to Jimma hubs, it will have limitation on representativeness of the agency as a whole.

Definition of key terms and concepts

• **Bundling** is the practice of integrating the supply of vaccines along with its consumables (diluents, injection and safety materials)

• **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.

• **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

• **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

Organization of the study

The thesis is organized into four 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, and significance of the study, scope of the study, imitation of the study, and definition of terms. The second chapter focuses on research design and methodology of the study. It de-

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

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 experience both the global and African perspective will also be addressed.

Theoretical Perspective

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 R., Roger M. and James Ch., 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, n.d.).

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 (EPSA, 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).

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" (Anonymous, n.d.) 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 (Anonymous, n.d.).

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 manu¬facturer's suggested timeline. CDC 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 (CDC, 2014).

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 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.

c. To light.

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

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

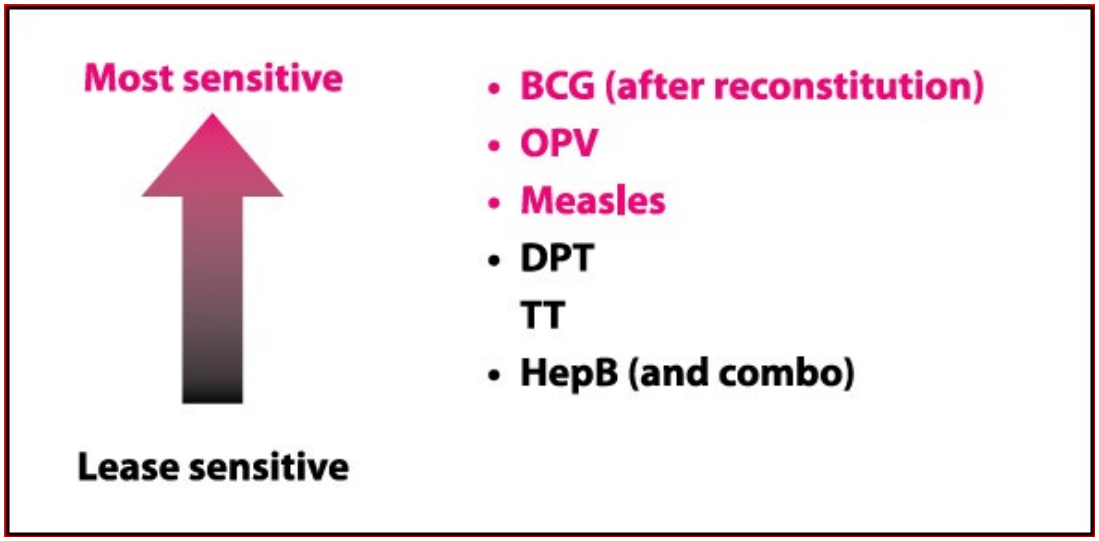

Figure 2: Sensitivity of vaccines for high temperature (UNOPS, n.d)

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

Some vaccines are very sensitive to light and lose potency when exposed to it. Such vaccines should always be protected against sunlight or any strong artificial light, and exposure should be minimized. Vaccines that are as sensitive to light as they are to heat include BCG, measles, measles-rubella, measles-mumps-rubella and rubella. These vaccines are often supplied in dark glass vials that give them some protection from light damage; but they should be kept in their secondary packaging for as long as possible to protect them during storage and transportation (WHO, 2005). Vaccines and cold chain equipment should be placed in such a way in the room that they are not exposed to sunlight any time during the day. Exposure to sun light will lead to 'increase in core temperature of the cold chain equipment, which would break the cold chain by causing an increase in the temperature of the vaccines (Naik A., Rupani M., & Bansal R., 203).

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 (Anonymous, n.d.).

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 responsi¬bility among man-

ufacturers, distributors, public health staff, and health-care providers. A proper cold chain is a tempera¬ture-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 imple¬menting best storage and handling practices, providers can ensure that patients will get the full benefit of vaccines they receive (Anonymous, n.d.).

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 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, and 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.).

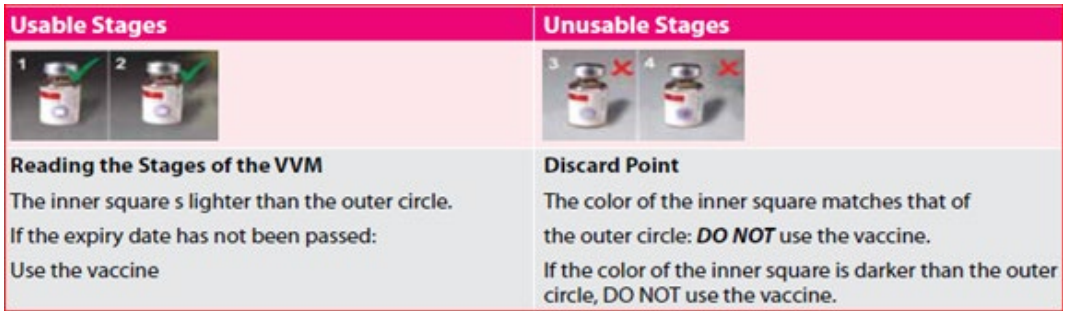

Figure 3: Reading the stage of VVM (UNOPS, n.d.)

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.).

Knowledge and practice on ISCM/staffing

One of the key supply chain components 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).

Empirical perspective

According to the recent WHO estimate, 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). A study conducted by NYU shows, 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 midway 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).

According to the WHO's 2011 report, 50 percent 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 levels 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 be 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 (Monicahetal., 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-degreeCelsius 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 (Monicahetal. 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 (Monicahetal. 2015).

According to WHO's 2012 report 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).

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 shall be in place 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 on Vaccine Supply Chain in Ethiopia was highlighting only on the impact of information system on improving quality of care.

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 or —vaccine supply chain in Ethiopia —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 EPSA hubs (FMOH, 2013). Therefore, as EPSA is new for vaccine management, there is a need to conduct a research on immunization supply chain practice in the EPSA context.

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 A, 2015).The researcher is going to assess the immunization supply chain practice, basically the key operations such as storage, handling, distribution of vaccines and temperature control on the cold chain. 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. Identifying the existing practice along each functional area at the agency can help to work on the supply chain gaps.

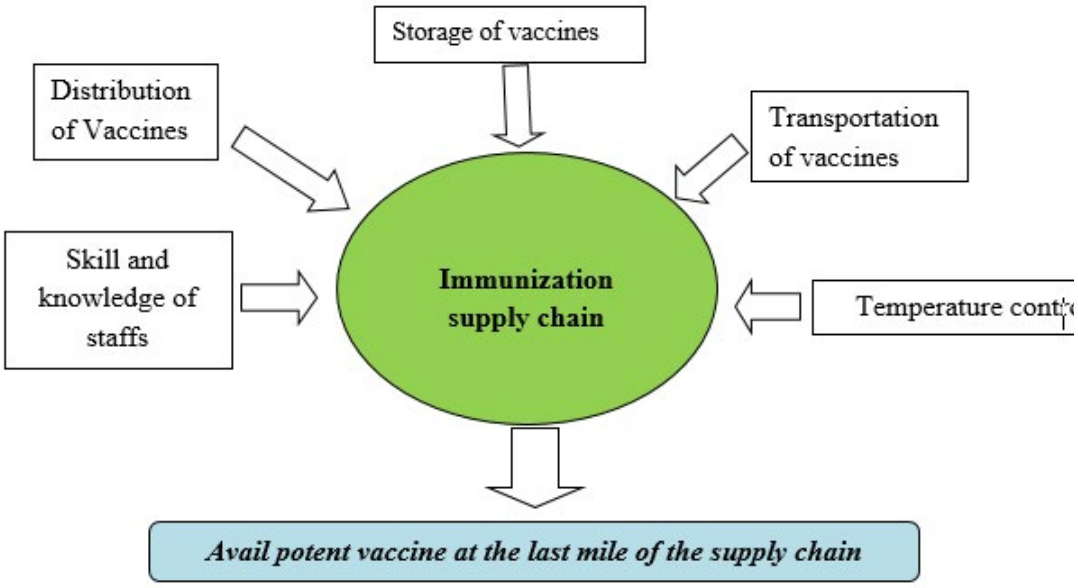

Figure 4: Conceptual framework of the study developed by the researcher

Methodology

Description of the study area

Ethiopian pharmaceuticals supply agency (EPSA) is legal entity established in 2007 by Proclamation No. 553/2007 based on the Pharmaceuticals Logistics Master Plan (PLMP). The Agency is mandated to avail affordable and quality pharmaceuticals sustainably to all public health facilities and ensure their rational use. There are 19 EPSA branches organized geographically in different corner of the country, rather than following administrative structure, to serve the public health facilities within 160Km radius, which improves service reliability and EPSA Jimma branch is located in south western part of Ethiopia with responsibility to serve public and private health facilities found in south western part of Ethiopia.

Clustering EPSA branches is a new initiative intended to coordinate, collaborate and accelerate the existing supply chain through a strong team spirit. Since its inception, the cluster system has accomplished several activities. Western Cluster is one of the seven clusters consisting of three branches: Jimma, Nekemte and Gambella and Jimma branch is selected to coordinate western cluster.

EPSA Jimma branch is the key governmental organization for the implementation of Integrated Pharmaceuticals Logistics System and distribution of vaccines and other health Program Pharmaceuticals for public and private facilities of Jimma, Bunobedelle, Illuababor, Kaffa, Bench Maji, Sheka, Mejenger Zone, Jimma Town administration, Konta Special Woreda and Yem Special Woreda. The study populations were staffs involved on immunization supply chain management. These are the stock and distribution coordinator, vaccine focal person, cold room managers, refrigerated truck drivers, vaccine delivery personnel and the CCE maintenance technician (EPSA, 2017).

Research approach

In this study, a combination of qualitative and quantitative approaches of doing research was employed to address the weakness and strength of both methods (Kothari, 2004). The quantitative ap-

proach was used to generate the data in quantitative form which can be subjected to rigorous quantitative analysis in a formal and rigid fashion. The qualitative approach was used to assess the subjective analysis of attitudes, opinions and behaviors of the respondents (Kothari, 2004).

Study Design

A descriptive research was conducted 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 is one-time research (cross-sectional) research.

Unit of analysis

Unit of analysis indicates the level at which the research is performed and which objects are researched or analyzed. Therefore, in this study, Jimma hub was 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. Cold room manager, vaccine focal, stock and distribution coordinators, cold van drivers and maintenance technicians were pertinent respondents in this study. These individuals are selected because they are the main actors on the vaccine storage, transportation and distribution from center to hub and from hub to health facilities. The target population is approximately 7 individuals.

Population of the study

EPSA Jimma was the study population. As a pilot site Jimma hub has better experience on vaccine management following the vaccine transition in 2014 (EPSA, 2014)

Sampling Procedure and Sample size determination

The study was conducted at EPSA Jimma branch. Purposive sampling methods were used because the hub has completed the Woreda level vaccine transition and have 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 (C.R. Kothari, 2004). Moreover, all staffs who directly engage on vaccine management were a respondent in this study. Therefore, census study by which a complete enumeration of each unit was assessed (Kothari, 2004)

- Warehouse and inventory management team leader
- Distribution officer/team leader
- Vaccine focal person
- Cold room managers
- Refrigerated truck driver
- CCE maintenance technician
- Vaccine delivery person

Therefore, the total sample sizes were the sum of all staffs engaged on immunization supply chain management, which is 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 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 are 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 addition, standard check list was developed to assess the storage and distribution practice.

Data analysis

In the assessment both qualitative and quantitative data was 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. SPSS mean and standard deviation was used to calculate and show the experts experience on immunization supply chain practices, and frequency and percentage were considered to present the respective practices and challenges.

Data presentation and interpretation were made using tables in order to display the collected data in a concise and meaningful way. Finally data were interpreted based on statistical findings.

Ethical Consideration

During data collection, all respondents were informed regarding the scope, purpose and anticipated outcome following the study, and any person who is not interested to participate on the interview will be dropped from the assessment. The information gathered from each respondent will be confidential.

Measurement instrument

Validity

To ensure validity of a study, a pilot study was conducted and the results were scrutinized. According to Kothari (2004) validity refers to the extent to which a test measures what we actually wish to measure. The purpose of a pilot study is to identify possible flaws in the measurement procedures such as ambiguous instructions and inadequate time limit of the intended study. Secondly, a pilot study identifies unclear or vaguely formulated statements. To test validity of the questionnaire, pilot study on ware house manager, vaccine focal person and Cold van driver was conducted. The three

persons given twenty-five minutes to complete the questionnaire and the researcher were assisted them. Respondents were asked to comment on the format and wording of the questionnaire. Any changes to the questionnaire after a pilot study may be required and taken immediately. A questionnaire was tested in order to ensure that all items are clear and understandable.

RESULT, DISCUSSION AND INTERPERTATION

The Chapter puts survey data in summarized form, discusses and interprets the research findings. The researcher gives interpretation of statistical results from the data. The demographic profile through descriptive statistics

Response rate

In this study seven participants (Warehouse and inventory management team leader, Distribution officer/team leader, Vaccine focal person, Cold room managers, Refrigerated truck driver, CCE maintenance technician and Vaccine delivery person) were selected and all are participated in the study.

Demographic data

The general demographic characteristics (age, gender, educational background and year of experience) of the respondents of the study were presented by using frequency statistics as follow.

Table 1: Demographic characteristics of respondents of the study on Vaccine Supply Chain and Logistics Systems in the Case of Ethiopian Pharmaceuticals Supply Agency Jimma Branch, 2019

Variables	Frequency	Percentage (%)
Gender of the respondents		
Male	5	71.4
Female	2	28.6
Age of the respondents		
18-25	1	14.3
26-35	6	85.7
Educational background of the respondent		
College Diploma	4	57.1
Bachelor's Degree	2	28.6
Postgraduate	1	14.3
Respondents years of experience in the agency		
1-5	4	57.1
6-10 years	2	28.6
More than 10 years	1	14.3
Source: Survey data (2019)		

As indicated in above table among 7 respondents 71.4 %(5) and 28.6 %(2) were male and female respectively. With regard to age of the respondents 14.3 %(1) and 85.7 %(6), of the respondents were in the age category of 18 to 25 old, and 26 to 35 old respectively. Concerning educational level 57.1 % (4), 28.6 % (2), and 14.3 %(1) were College Diploma, Bachelor's Degree and Postgraduate respectively. The respondent's experience in the job were found to be 1 to 5, 6-10 and more than 10 years for 57.1% (4), 28.6% (2), and 14.3 % (1) of the respondents' respectively with most of them spent 1-5 years in EPSA Jimma. The general characteristic of the respondent gives the clue that respondents have the necessary understanding and knowledge about subject matter and understand the objective of the study to respond each item in questionnaire.

Results/Findings

Description of vaccine storage practice in Ethiopian pharmaceuticals supply agency Jimma branch

Respondents were asked to rate the vaccine storage practice on a five-point Likert scale (strongly disagree, disagree, neutral, agree and strongly agree). The mean was computed and utilized with the following assumption: if the mean value is between 0 to 1.5 this implies the respondents strongly disagreed, if the mean value is between 1.5 to 2.5 it implies the respondents' disagreed, if the mean value is between 2.5 to 3.5 it implies the respondents were neutral, if the mean value between 2.5 to 3.5 it implies the respondents were neutral, if the mean value between 3.5 to 4.5 implies the respondents' agreed and a mean value 4.5 and above indicates the respondents' strongly agreed

Table 2: The mean and standard deviation values for adequacy Vaccine storage

Statement	N	Mean	Std. Deviation
There is adequate positive storage space for vaccines	3	4.6667	.57735
There is adequate negative storage space for vaccines	3	2.0000	0.00000
There is temperature monitoring device in the cold/freezer room	3	3.0000	1.00000
Daily temperature monitoring practice is in place (temperature recorded twice daily)	3	4.0000	0.00000
There is backup generator in case of power outage	3	2.3333	.57735
There is contingency plan in case of cold room failure	3	4.3333	.57735
There is proper CCE maintenance structure for corrective and preventive maintenance	3	3.6667	.57735
Safety warehouse clothing is in place	3	4.0000	0.00000
Source: Survey data (2019)			

The above table presented adequacy of storage capacity, responses computed for mean and standard deviation. The respondents remained neutral on availability of temperature monitoring device in the cold/freezer room (mean=3.00, SD=1.00), disagree on availability of adequate negative storage space for vaccines (mean 2.00, SD=0.00) and backup generator in case of power outage (mean=2.33 and, SD=0.577). But they agreed on Daily temperature monitoring practice is in place (mean=4.00, SD=0.00), contingency plan in case of cold room failure (mean=4.33, SD=0.577), and Safety warehouse clothing is in place (mean=4, SD=0.00) and the respondents were strongly agreed for adequacy of positive storage space for vaccines (mean =4.66, SD=0.577).

A document review shows that 265,568 births infant, 246,435 surviving infants, were rendering services from the hub, and there is 90m3 gross volume of positive storage (+2 to +8 degree Celsius), accordingly to WHO recommendation the available storage space is adequate.

Distribution and Transportation of Vaccines

The following table indicates the mean and standard deviation for all items used to describe distribution and transportation system.

Table 3: The mean and standard deviation from survey data-distribution and transportation of vaccines

Statement	N	Mean	Std. Deviation
There is adequate number of vehicle for transportation of vaccines	7	3.1429	1.34519
Refrigerated vehicle pre cold before loading of vaccines	7	2.0000	.81650
The temperature of vaccine is always monitored during transportation	7	1.1429	.37796
There is bundling practice during distribution of vaccines (integrating vaccine with its consumables)	7	3.8571	.69007
Source: Survey data (2019)			

As presented on the above table respondents agreed on bundling practice during distribution of vaccines (mean=3.8571, SD=0.69007), Disagree on Refrigerated vehicle pre cold before loading of vaccines (mean=2.0000, SD=0.81650), whereas strongly disagree on temperature of vaccine is always monitored during transportation (mean=1.1429, SD=0.37796) and availability of adequate number of vehicle for transportation of vaccines (mean=3.1429, SD=1.34519) for which respondents remained neutral.

Knowledge of staff on vaccine management

Respondents were asked question for the recommended temperature range for most vaccine stored and transported in degree Celsius and results are summarized in figure 1.

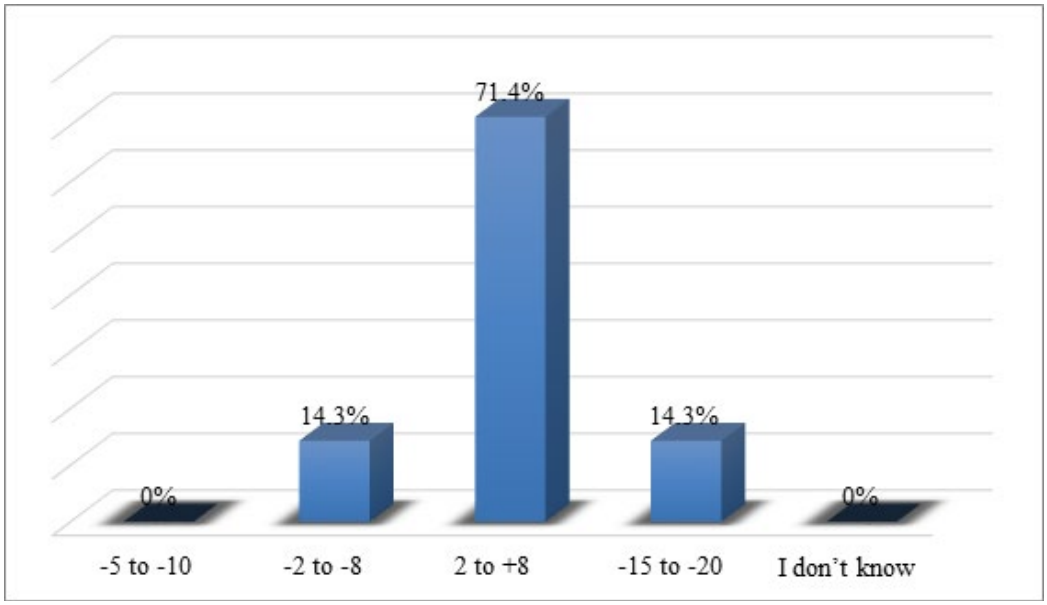

Figure 1: Knowledge level of respondents on recommended temperature range for most vaccines stored and transported in degree Celsius.

Majority (71.4%) of respondents had knowledge on recommended temperature range for most vaccines stored and transported and (28.6%) of the respondents had no knowledge on recommended temperature range for vaccines stored and transported

Table 4: Knowledge of Respondents on Sensitivity of Vaccines to Freeze and Light, Shake Test, Vaccine Vial Monitor (VVM), WHO MDV Policy and Conditioning Ice Pack, Vaccine Supply Chain and Logistics Systems in the Case of Ethiopian Pharmaceuticals Supply Agency Jimma Branch, 2019.

Statement	Frequency	Percentage (%)
Knows highly freeze sensitive vaccine	4	57
Knows Vaccine highly sensitive for light?	3	43
Knows the vaccine to be stored in freezer room	5	71
Knows about shake test	2	29
Knows about Vaccine Vial Monitor (VVM)	6	86
Knows WHO multi dose vial policy	1	14
Knows conditioning of ice pack	5	71

A majority 6 (86%) knew the correct definition for Vaccine Vial Monitor (VVM), 5 (71%) knew the vaccine to be stored in freezer room and conditioning of ice pack. The knowledge of shake test and WHO multi dose vial policy was poor among a higher proportion of respondents, 5 (71%) and 6 (84%), respectively. Just over half of the respondents 4 (57%) had poor knowledge of freeze sensitive vaccines. Respondents trained on vaccine management had better knowledge of vaccine vial monitor (VVM) 6 (86%), 5 (71%) knew conditioning of ice pack and 5 (71%) knew the vaccine to be stored in freezer room than untrained staffs.

Staffing Training and Organizational Support

Table 5: Training status of Respondents on different areas of vaccine management, Vaccine Supply Chain and Logistics Systems in the Case of Ethiopian Pharmaceuticals Supply Agency Jimma Branch, 2019.

Training on	Frequency	Percentage (%)
Correct storage temperatures;	6	86%
Vaccines damaged by freezing;	3	43%
Vaccines which can be frozen	4	57%
Vaccines which must be frozen;	4	57%
VVM reading	7	100%
Shake test	2	29%
Temperature monitoring using the range of available devices	6	86%
Storage of diluents	5	71%
How to arrange vaccines in cold rooms, freezer rooms, refrigerators and freezers	6	86%
Icepack conditioning	5	71%
Cold box/vaccine carrier packing	6	86%
On average 70% of employee had on service training. As indicated on above table all respondents were trained on VVM reading (100%).		

Vaccines Storage and Handling Practice

One to one interview and document review

From one to one interview and document review, the investigator has observed as continuous temperature loggers that track and record cold room, refrigerator and freezer temperature were not available to any of the storage facilities and the there is no complete set of temperature record. Temperature-sensitive alarms that alert the cold chain officer via SMS during prolonged exposure to out-of-range temperatures were also not available at the storage areas. Temperature mapping and devices calibration was not done for all cold rooms, freezers and refrigerators. The correct number and placement of ice packs inside the cooler is important because too few ice packs can fail to maintain the internal cooler temperature and too many ice packs have the potential to freeze the vaccine and in this facility it is found to be sufficient storage capacity fore icepacks.

A written contingency plan in case of equipment failure, natural disaster, or major power outage should be available. The contingency plan, prepared well in advance, should be prominently located, be freely accessible, and include: Contact information for the relevant stakes, their role and the elements or conditions. In the study area there was well organized contingency plan was in place.

Interpretation and Discussion

The result above showed that there are rooms for improvement in order to ensure recommended good storage. Although respondents agree on all items with some variables like availability of storage equipment for different vaccine, contingency plan development and implementation of SOP are relatively on lower scale in this range. Close control of storage condition should be strict rather than option. Control of storage conditions and temperature is essential in maintaining the quality of cold chain items and in helping to protect patients from sub-standard or ineffective medicines that may result from inadequate storage control (CDC, 2014). For measuring vaccine storage unit temperatures, CDC recommends using only calibrated temperature monitoring devices with a Certificate of Traceability and Calibration Testing (also known as Report of Calibration). Calibration testing should be performed every 1 to 2 years or according to manufacturer's suggested timeline. Temperature mapping should be done for all storage areas (CDC, 2014).

Vaccines need specialized storage because of the very sensitive nature of these biological products. As a result, the type of equipment used for storing vaccines needs to be specialized according to different temperature zones, and the service level of storage. Storage capacity needs to be sufficient to meet the immunization needs, and transport containers must keep the vaccines in optimal condition throughout the journey. The study was concerned about one aspect of cold storage whether or not the existing storage capacity is adequate to accommodate all vaccines (4 months stock with 25% buffer stock in relation to its target population) need.

This assessment, therefore, tried to calculate the storage capacity based target population, birth infant (265,568) and surviving infant (246,435) for all available cold stores (Cold rooms, refrigerators and freezers) and compared with WHO recommended storage capacity needed and the branch has sufficient positive (+20C to +8 0C) storage capacity, but the available negative storage volume only covers 65% of negative storage capacity needed (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). The distribution system of vaccines is concerning with maintaining of the cold chain. The cold chain is the system of transporting and storing of vaccine at the recommended temperature range which is (+2°C to+8°C for refrigerator vaccines) and (-15°C to -25°C for freezer vaccines).

In this study respondents agreed on bundling practice during distribution of vaccines, Disagree on Refrigerated vehicle pre cold before loading of vaccines, whereas strongly disagree on temperature of vaccine is always monitored during transportation and availability of adequate number of vehicle for transportation of vaccines for which respondents remained neutral. Similar study conducted in coast region, Tanzania showed that the main cause of delay in delivery of vaccines to the health centers was shortage or lack of transport to distribute the vaccine. As indicated in similar study lack of reliable transport at district level contributes to shortage of vaccines at health facility level (Makuru M., 2012).

To maintain vaccines perfectly conserved from its manufacture through administration requires an adequate cold chain infrastructure, compliance to standards and effective management. At the end of the chain staffs that managing the vaccines must have adequate knowledge to manage the cold chain. To improve management, the World Health Organization (WHO) has created a set of practice guidelines for different service levels, which include immunization techniques, vaccine monitoring, cold chain management and reporting systems (WHO, 2014). The study was tried to asses the Knowledge of respondents on vaccine management on each routine vaccine, appropriate storage conditions (temperature range), stages of changes in Vaccine vial monitors (VVM) and actions to be taken on vials with changed VVM, shake test, WHO MDV and ice pack conditioning. Majority respondents knew the correct definition for vaccine vial monitor (VVM), the vaccine to be stored in freezer room and conditioning of ice pack. The knowledge of shake test, and WHO multi dose vial policies was poor among a higher proportion of respondents.

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).

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 manu¬facturer's suggested timeline. CDC 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 (CDC, 2014). 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). In study area there is no systematic temperature monitoring, a complete set of manual temperature records/ temperature logger printouts for each and every cold room, refrigerated vehicle, vaccine refrigerator and vaccine freezer and there temperature records formally reviewed at least once a month in order to identify temperature excursions and their causes and temperature mapping and a test calibration were not done for all devices.

Conclusion And Recommendation

Conclusions

There are rooms for improvement in order to ensure recommended good storage. Although respondents agree on all items with some variables like availability of storage equipment for different vaccine, contingency plan development and implementation of SOP are relatively on lower scale in this range but temperature mapping and devices calibration was not done for all cold rooms, freezers and refrigerators.

Regarding the storage capacity, the storage capacity was calculated based target population, birth infant (265,568) and surviving infant (246,435) for all available cold stores (Cold rooms, refrigerators and freezers) and compared with WHO recommended storage capacity needed and the branch has sufficient positive (+20C to +80C) storage capacity, but the available negative storage volume only covers 65% of negative storage capacity needed.

The respondents agreed on bundling practice during distribution of vaccines, Disagree on Refrigerated vehicle pre cold before loading of vaccines, whereas strongly disagree on temperature of vaccine is always monitored during transportation and availability of adequate number of vehicle for transportation of vaccines for which respondents remained neutral. Majority respondents knew the correct definition for vaccine vial monitor (VVM), the vaccine to be stored in freezer room and conditioning of ice pack. The knowledge of shake test, and WHO multi dose vial policies was poor among a higher proportion of respondents.

In study area there is no systematic temperature monitoring, a complete set of manual temperature records/ temperature logger printouts for each and every cold room, refrigerated vehicle, vaccine refrigerator and vaccine freezer and there temperature records formally reviewed at least once a month in order to identify temperature excursions and their causes and temperature mapping and a test calibration were not done for all devices.

Recommendations

- EPSA and development partners should have to work more to improve storage practices, by providing on job training/class room training, continuing supportive supervision, by Temperature mapping and calibrating cold rooms, freezers and refrigerators
- EPSA and development partners working in immunization logistics and supply chain management should invest more on negative cold store devices.
- EPSA need to strengthen the transport system of cold chain vaccines according to their optimum temperature ranges, because the temperature may affect their quality.
- PFSA – Need to supply freezer tags to all cold chain warehouses which can help in monitoring and recording temperature even when the store managers in charge were absent.
- There must be a systematic temperature monitoring study been carried out for the cold rooms.
- There must be a complete set of manual temperature records for each and every cold room, freezer room, vaccine refrigerator and vaccine freezer.
- There must be a complete set of temperature recorder traces and/or temperature logger printouts for each and every refrigerated vehicle.
- Temperature records should be formally reviewed at least once a month in order to identify temperature excursions and their causes.

Suggestion for further study

This study just focused on logistics and supply chain management practices in the case of EPSA Jimma, further research can be carried out to cover the all EPSA branches to assess the magnitude of the problem.

Declaration

I, Tekalign Admasu, declare that this thesis work entitled "assessment on vaccine supply chain and logistics systems in the case of Ethiopian pharmaceuticals supply agency Jimma branch" is my original work. I also declare that it has never been presented in this or any other author/researcher and that all resources and materials used in the thesis have been duly acknowledged.

Acknowledgement

I would like to thank all people who directly or in directly helped me in this work. Special thanks go to Dr. Dereje Tefera for his guidance and unwavering support in shaping and providing valuable insights for the study. My heartfelt appreciation goes to my wife Fasika Tamirat for her all-rounded support and entire burden sharing from day one to the end during my years of study. Lastly, I would also like to thank my friends and colleagues for their support and constant encouragement.

Statement of data availability

The primary and secondary data used to support the findings of this study are included within the supplementary information file (excel (SPPS file), interview documents and reviewed documents copy was available at the end of the paper)

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
EPSA: Ethiopian Pharmaceutical 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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