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Assessment of vaccine provider's knowledge, and attitude, and private health facilities compliance with World Health Organization requirement of vaccine management practice, Addis Ababa, Ethiopia.

By

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This is to certify that the thesis prepared by Lake Alemayehu Bitew, entitled: Assessment of vaccine providers' Assessment of vaccine provider's knowledge, and attitude, and private health facilities compliance with World Health Organization requirement of vaccine management practice, Addis Ababa, Ethiopia, and submitted in partial fulfillment of the requirements for the Degree of Master of Science in health supply chain management complies with the regulations of the University and meets the accepted standards concerning originality and quality.

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List of Abbreviations

AACAHB	Addis Ababa City Administration Health Bureau
BCG	Bacillus Chalmette Guerin
CCE	Cold Chain Equipment
CCT	Controlled Cold Temperature
CDC	Centers for Disease Control and Prevention
DT	Diphtheria and Tetanus toxoid
EPI	Expanded Program on Immunization
EVM	Effective Vaccine Management
FMOH	Federal Minister of Health
GHF	Governmental Health Facilities
HF	Health Facility
Hib	Haemophilus Influenza Type b
IPV	Inactivated polio Vaccine
MCH	Mother and Child Health
MDVP	Multi-Dose Vial Policy
NGOs	Non Governmental organizations
OPV	Oral Polio Vaccine
PCV	Pneumococcal Conjugate Vaccine
PHFs	Private Health Facilities
PI	Principal Investigator
SDP	Service Delivery point
SOPs	Standard Operating Procedures
TDT	Tetanus and Diphtheria Toxoid
TMS	Temperature Monitoring Studies
TT	Tetanus Toxoid
UNICEF	United Nations Children's Fund
VVM	Vaccine Vial Monitoring
WHO	World Health Organization

Abstract

Introduction: Vaccines are exceedingly efficient biological substances and the first lines of public health strategies against infectious diseases. Due to the sensitive nature of vaccines, appropriate measures need to be put in place to ensure that vaccines remain potent from point of manufacture to administration.

Objective: To assess vaccine provider's knowledge, and attitude, and private health facilities compliance with World Health Organization requirement of vaccine management practice, Addis Ababa, Ethiopia.

Methods: Cross-sectional study design was employed to collect data using a structured questionnaire and observation tools in the private health facilities offering immunization services in Addis Ababa. The study was conducted from March to July 2020. Data were analyzed by SPSS and the result was presented by frequency and percentage in the form of tables and graphs.

Result: Thirty private health facilities were included in the assessment and, only 3(10%) had WHO prequalified functional refrigerators, while 90% of the facilities had domestic types of refrigerators. Of the 34 study participants who participated in the study, 7(20.6%) respondents had poor knowledge of vaccine cold chain management while 26 (76.5%) had a positive attitude toward vaccine cold chain management. Determinants of knowledge on vaccine cold chain management training were (P = 0.042), and supportive supervision (P = 0.026). The knowledge of healthcare workers towards the vaccine cold chain management was significantly associated with the health workers' training and supportive supervision in health facilities. Determinants of attitude on vaccine cold chain management training were (P= 0.019) and supportive supervision was (P= 0.043). The attitude of healthcare workers towards the vaccine cold chain management was significantly associated with the health workers' training and supportive supervision in health facilities.

Conclusion: This study indicates that WHO standard refrigerators are available only in some health facilities for vaccine storage. There was also a gap, in training, knowledge, and attitude of vaccine providers toward vaccine management, and inappropriate vaccine management practice. Therefore, there is a need to improve cold chain management.

Keywords: Vaccine cold chain management, vaccine providers, knowledge, and attitude.

1. INTRODUCTION

1.1 Background

Around 29,000 children under the age of five die each day worldwide mainly due to vaccine-preventable diseases. From these deaths, most occur in developing countries, especially in Africa. These diseases kill about 470,000 children of Ethiopia per year and an Ethiopian child has 30 times the probability of death by his or her fifth birthday than a child found in Western Europe (UNICEF, 2005).

To save the lives of millions of infants and young children dying from vaccine-preventable diseases, namely tuberculosis, tetanus, whooping cough, diphtheria, poliomyelitis, and measles, the Expanded Programme on Immunization(EPI) was launched by WHO in 1974(Lugosi and Battersby,1990). Ethiopia adopted EPI in 1980 but the current Ethiopian immunization policy was updated in 2007. Children of the under-one year of age and women of a reproductive age group (15-49 years age) are the targets for the EPI vaccines. Bacillus Chalmette Guerin (BCG), Measles, pentavalent vaccine, Diphtheria, and Tetanus toxoid (DT), Oral Polio Vaccine (OPV) and Tetanus Toxoid (TT) vaccine are available in Ethiopia and currently two other vaccines; Pneumococcal Conjugate Vaccine (PCV), as well as Rotarix, has been added. The multi-dose open vial policy (MDVP) and the exclusive use of only Auto Disable (AD) syringes for delivering all immunization injections was adopted in 2002 (Kidane *et al.*, 2008).

Achieving high coverage rates of immunization is considered as one of the parameters to measure the success of the immunization program. However, disease reduction is the ultimate goal of EPI mainly on the provision of a potent and safe vaccine to the children(Lugosi and Battersby, 1990). Vaccines are exceedingly efficient biological substances and the first lines of public health strategies against infectious diseases. Due to the sensitive nature of vaccines, appropriate measures need to be put in place to ensure that vaccines remain potent from point of manufacture to administration (WHO, 2006), they lose their potency exposed to temperatures outside the required range which could result in reduced immune responses and inadequate protection against disease; all health professionals have a responsibility to ensure that vaccines are potent, safe and effective when children are being immunized to ensure high levels of disease control and public confidence in vaccine programs (WHO,2012).

Several reports from developing countries indicate that health workers seem to be overwhelmingly concerned with only raising vaccination coverage. The quality of vaccination services that is equally important for the achievement of the ultimate goal of disease reduction has been neglected. Suboptimal seroconversion rates and outbreaks of vaccine-preventable diseases elsewhere were attributed to the loss of vaccine potency either during transportation or storage (Berhane and Demissie, 200).

The system of transporting, storing, and distributing vaccines in a potent state at the recommended temperature range from the point of manufacture to the point of administering is the vaccine cold chain management. Vaccine potency once lost cannot be restored(WHO, 2012). The common vaccine Cold chain components are equipment for transport and storage, trained personnel, and efficient vaccine management practices. The common elements of all cold chain systems are a series of storage and transport links through a network of fridges, freezers, and cooler boxes that keep vaccines at an optimum temperature, which is +2 to +8 °C (WHO, 1998).

vaccine vial monitor (VVM) is a label containing a heat-sensitive material that is placed on a vaccine vial surface to register cumulative heat exposure (WHO, 2006). The VVM is a very important point for the health worker to know whether the vaccine was damaged by heat or not (Grasso *et al*., 2003). The cold chain management should give attention and emphasis to achieve this aim (Yakum *et al.*, 2015) and maintain otherwise, cold chain failure will happen such as VVM changes, freezing, and vaccine-preventable diseases might occur on the child (Bateman, 2016). Therefore it is important to enhance health worker knowledge to monitor equipment maintenance and safe temperature storages (Zaffran *et al*., 2013).

The basic principles to make sure vaccine storage and proper maintenance of cold chain are the availability of trained staff, appropriate vaccine transport, and standard vaccine storage refrigerators (Craig, 2008). Trained personnel for the management of the vaccine cold chain is usually available in developed countries than in developing countries (Ortega, 2007), and their performing daily temperature monitoring in health facilities accounted for two to three times more likelihood (Karen *et al*., 2001). Staff who handle and administer vaccines should receive training regarding vaccine storage and handling policies and procedures. Training should also be integrated into orientation programs (WHO, 2012). To improve vaccine management practices,

WHO has created different practice guidelines for different service levels, such as immunization techniques, vaccine monitoring, cold chain management, and reporting systems (Chiodni, 2014).

There are numerous challenges in the management of the cold chain of vaccines despite the many advances in immunization in Ethiopia. These include insufficient financial resources, a shortage of trained staff, and a lack of knowledge of vaccine providers regarding vaccine management. These challenges will lead to vaccines becoming compromised and less potent(FMOH, 2013). Inadequate knowledge of healthcare workers on vaccine management could lead to improper handling of vaccines which would result in altered potency of vaccines. In addition to knowledge, the attitude of health workers toward cold chain management is a pointer to how committed they are in ensuring knowledge acquired is translated into effective practice (Joao, 2007). Hence, this study would be conducted to assess the vaccine management practice and knowledge and attitude of vaccine providers in private health facilities in Addis Ababa city Administration.

1.2 Statement of the Problem

Improper management and use of outdated refrigeration equipment, poor compliance to cold chain procedures, inadequate monitoring, and poor understanding of the effect of vaccine freezing contribute to the weakness of the cold chain management in many countries (Joao *et al*., 2007).

Many global studies showed that attention to the maintenance of correct temperature monitoring practice during storage, transportation, and use of vaccines is a challenge for the health workers /health workforces (Wang *et al.*, 2007).

Studies conducted in Malaysia in public health facilities showed that most (75%) of respondents or health workers had a negative attitude toward cold chain management (Azira *et al*., 2013).

Studies on the knowledge, attitudes, and practices of private immunization service providers in India, Nigeria, and Korea identified almost all the private immunization service provider's stored vaccines in domestic refrigerators and some stored vaccine vials in unrefrigerated thermal boxes, the respondents had poor knowledge of vaccine cold chain management and awareness of health workers were inadequate for cold chain management (World Bank, 2008; Dairo *et al*., 2016).

A study conducted in private health facilities in Colombia showed that almost 90% of facilities stored vaccines in electric refrigerators; however, 75% of the health facilities stored vaccines without temperature monitoring devices. (Sann, 2008)

The studies conducted in low-income countries showed that the private for-profit health sector is contributing to immunization service delivery and helping to improve access to traditional EPI. But governments did not give attention to monitoring vaccine storage management and the quality of immunization services (Levin and Kaddar, 2011).

In low and middle-income countries quality of immunization service provision monitoring and supervision of private provider vaccination delivery and participation in an adverse event and disease surveillance activities are often inadequate (Levin and Kadda, 2011)

Cold chain monitoring is a major challenge in many developing countries such as Tanzania because of poor transportation infrastructure, unreliable electricity supply, shortage of trained personnel, and proper equipment to store temperature-sensitive commodities (WHO, 2006).

In Ethiopia, the study conducted in public health facilities revealed that vaccine storage in the refrigerator was not proper in 73.4% of the centers. Most of the health centers had neither trained personnel nor a budget for maintenance of the cold chain (Berhane and Demissie, 2000).

Research conducted at public health facilities in Nekemit town and Bale zone showed that there was a problem with the proper storage of vaccines and gaps in knowledge about vaccine storage management. Most of the respondents did not know in which compartment of the refrigerator each vaccine was stored and 44% of the respondents did not comply with storage temperature as per the national standard. They also did not keep the cold chain medicines in a refrigerator or freezer under the recommended temperature range during storage(Fekadu *et al*., 2018; Woldemichael *et al*., 2018).

Research conducted at private health facilities in Addis Ababa showed that the distribution system and the information system affect the availability of vaccines (Firomesa, 2018), but the research did not address vaccine wastage rate, knowledge, attitude, availability of standard cold chain equipment, and challenges related to vaccine management practices of the private health facilities. So, to address the gaps, this study was intended to incorporate the attitude, knowledge, availability of standard refrigerators, and to assess vaccine management practices in private health facilities. There are several studies in Ethiopia regarding vaccine cold chain management but most of them focus on public health facilities(Woldemichael *et al*., 2018; Fekadu *et al*., 2018; Ismail, 2008).

Therefore this study could provide empirical evidence of the vaccine management practice, knowledge, attitude of the immunization focal person, and current status of vaccine management practices in private health facilities. And it also provides information to improve vaccine and diluent handling and storage practices to the responsible body.

1.3 Research Questions

1. How was the vaccine providers' knowledge towards vaccine management in private health facilities compared to WHO standards?
2. How was the attitude of vaccine providers' towards vaccine management in private health facilities compared to WHO standards?
3. What was the current practice of vaccines management in the private health facilities, Addis Ababa?

1.4 Significance of the Study

This study provides information on the vaccine and diluents handling and storage condition. And it could also provide insight into further research needs in this area.

This study results could reinforce the existing knowledge of the cold chain management of vaccines. The study would highlight gaps that exist in the vaccine cold chain system and the processes of vaccine management would be identified. The recommendations would be important to the decision-makers for the improvement of vaccines and diluents storage and handling strategies and operations. The results would assess the vaccines and diluents cold chain management system.

1.5 Scope of the Study

The scope of the research is the assessment of vaccine management practice, knowledge, and attitude of vaccine providers with the WHO standards or requirements at private health facilities, in Addis Ababa, Ethiopia.

2. Literature Review

2.1 Theoretical Literature Review

2.1.1 Vaccine Management System

Vaccination is one of the foremost effective disease prevention strategies and the potency of the vaccine depends on effective management of cold chain the least bit levels of vaccine handling. A good cold chain maintenance system is the backbone of the success of any immunization program. Vaccines are heat-sensitive biological substances that with time lose their potency, especially when exposed to heat, sunlight, and cold. Once a vaccine's potency has been lost, it could not be restored and way not prevent the disease (Mugharbel *et al*., 2009).

According to vaccine and diluent storage WHO guidelines the freeze-sensitive vaccines include: Diphtheria; Tetanus and cellular pertussis; Hepatitis B Haemophilus influenza type B Inactivated polio Vaccine (IPV), Meningococcal, Pneumococcal, Human Papillomavirus, Rotavirus; and Vaccine Diluents.

The most heat-sensitive vaccines are Measles Mumps Rubella**,** OPV**,** BCG, and Chickenpox.

This emphasizes the importance of the cold chain system within an immunization programmed as it ensures that vaccines are maintained at the correct temperatures and thus, guarantees the effectiveness of vaccines in such programs. Vaccines are biological products that lose their potency over time and this will result in reduced immune responses and inadequate protection against disease; vaccine providers, pharmacists, and managers have a professional responsibility to ensure that vaccines are potent, safe, and effective when children are being immunized to ensure high levels of disease control and public confidence in vaccine programs(WHO,1998). Vaccines are expensive and healthcare professionals have a responsibility to not waste this scarce resource. The safety of the vaccine is linked to the adverse events following the immunization program (Craig, 2008). Therefore cold chain store employees and managers involved in the cold chain system must ensure every effort is made to retain the safety of vaccines.

2.1.2 Policy and Guideline on Vaccine Management

According to the Vaccine Storage and Handling Toolkit immunization programs and practices must have written protocols for routine storage and handling and emergency procedures for the cold chain management of vaccines (WHO, 2012). The Vaccine Storage and Handling Guide

(WHO, 2014) states that staff should be knowledgeable regarding vaccine storage and handling. There should be at least two staff members who are responsible for vaccine management in each facility.

2.1.3 The Storage and Handling of Vaccines

Vaccines exposed to temperatures outside the recommended ranges (+2°C to +8°C) may reduce their potency, safety, and prevention. Storage and handling errors may increase the cost of vaccines and revaccination(WHO, 2015). Vaccines are heat sensitive. Therefore it must be store at the recommended temperatures by WHO and by the vaccine manufacturers and protected from light at every point in the cold chain. (WHO, 2015).

2.1.4 Cold Chain Equipment

WHO recommends stand-alone refrigerators or freezers and purpose-built refrigerators for storing vaccines, most domestic refrigerators are not fan-forced and have poor temperature recovery after the door has been opened. Standard vaccine refrigerators control temperatures and will alarm if the temperature goes out of specifications(WHO, 2016). It also records minimum and maximum temperatures. It is recommended that vaccines must be stored at a temperature range between two to eight degrees Celsius (WHO, 2012).

The correct number and placement of ice packs inside the cold box are important as too few ice packs can fail to maintain the internal cold box temperature. The recommendations state that a thermometer must be placed in the cold box next to the vaccines and the temperature of the cold box must be monitored hourly (Rogers *et al.*, 2010). By monitoring the temperature hourly the vaccine providers will be able to identify if vaccines are still potent and safe to use.

The national vaccine storage guidelines strive to state that no food or any other goods must be stored in the refrigerator. This ensures that staff do not continuously open and close the refrigerator door unnecessarily, causing fluctuation in fridge temperatures, ultimately causing vaccines to become compromised (WHO, 2014).

The vaccine storage capacity of cold boxes is between 5.0 and 25.0 liters. There are two types of cold boxes: 1. Short-range cold boxes: With a minimum cold life of 48 hours, 2. Long-range cold boxes: With a minimum cold life of 96 hours(WHO, 2014).

2.1.5 Maintenance of Cold chain Equipment

The warehouse should implement a maintenance program for all temperature-controlled rooms, cold rooms, freezer rooms, refrigerators, and freezers: Carry out regular planned preventive maintenance on all temperature controlling equipment, Make arrangements to ensure that emergency maintenance is carried out within a period that does not place temperature-sensitive products at risk of damage, ensure that there are regular maintenance and records to demonstrate compliance (WHO, 2012).

2.1.6 Challenge Faced in Vaccine Management

There are numerous challenges in the management of the cold chain of vaccines despite the many advances in immunization in Ethiopia. These include insufficient financial resources, a shortage of trained staff, and a lack of knowledge regarding vaccine management. These challenges will lead to vaccines becoming compromised and less potent. Some solutions to overcome these challenges may be training, supervision, and regular auditing to improve the performance of vaccine management (WHO, 2006).

Lack of accountability for vaccines stock monitoring, absence of sensitive vaccine wastage monitoring indicator, lack of clear vaccine distribution plans, lack of budget specifically allocated for vaccine transportation at all levels and inaccurate use of temperature monitoring devices are some of the challenges in the vaccine management system in Ethiopia (FMOH, 2013)

2.1.7 Record-Keeping of Vaccines Stock

All facilities must have written policies, procedures, and protocols in place regarding vaccine management. Records must be maintained on vaccine balances, waste, refrigerator temperature, refrigerator servicing, and records of training of staff on vaccine management. Proper documentation helps to prevent stock out and wastage of vaccines (WHO, 2012).

2.1.8 Training and Supportive Supervision

All workers who receive deliveries and handle or administer vaccines and diluents ought to be acquainted with storage and handling policies and procedures at the facility. Standard Operating Procedures (SOPs) for storage and handling should be kept near storage units and make sure the staff knows where to find them (CDC, 2018).

The Vaccine Storage and Handling Toolkit and the National Vaccine Storage Guidelines recommend that staff who handle and administer vaccines should receive training regarding vaccine storage and handling policies and procedures continuously. Training should also be integrated into orientation programs (WHO, 2012).

2.1.9 Vaccine Vial Monitor

The Vaccine Vial Monitoring(VVM) is that the sole tool among all time-temperature indicators that's on the market at any time within the method of distribution and at the time an immunogenic is run, indicating whether or not the immunogenic has been exposed to a mixture of excessive temperature over time and whether or not it is broken. It indicates whether or not an immunogenic may be used (WHO, 2014). Though developed as a heat-exposure indicator, VVM additionally contributes considerably to the reduction of immunogenic chilling since it permits medical examiners to ascertain the warmth stability of vaccines and settle for the very fact that chilling could be a bigger danger than delicate heat exposure (WHO, 2014).

2.2 Empirical Literature Review

2.2.1: Global Perspective on Cold Chain Management Practice

For vaccine cold chain management to be efficient, three major elements are required. Well-trained personnel, reliable transport or storage equipment and, efficient management procedures are the major components. An absence of any of these elements would lead to poor cold chain management systems (Ogboghdo *et al*., 2018). Too much exposure to heat, cold, or light of vaccine and other cold chain medicines at any step in the cold chain management can damage the products, and resulting in loss of vaccine potency, and once lost, potency cannot be restored. Each vaccine is exposed to improper conditions, potency is reduced further (CDC, 2018).

Many world studies, like those conducted in Vietnam by (Hip grave *et al*., 2006) and in China by (Wang *et al*., 2007) have found that the spotlight on the maintenance of correct temperatures throughout storage and the use of vaccines could be a challenge for employees. Consistent with these studies' challenges that workers face was because of non-competent personnel managing the vaccines, instrumentation used for vaccine management not being effective and procedures not being economical.

Studies also reported that improper vaccine storage leading to the administration of sub-potent vaccines was associated with outbreaks of vaccine-preventable diseases in Israel and several developing countries (Dairo, 2016).

2.2.2 Attitude and Knowledge of Vaccines Management

Evidence from studies conducted in Malaysia revealed that 75% of respondents or health workers had a negative attitude toward cold chain management, and about 75-85% of respondents agreed to put an adequate number of ice packs within the cold box to take care of the standard temperature, should label 'Open When Needed' at the vaccine refrigerator door to reduce exposure to heat. For good vaccine management practice, only 4.5% of the respondents believed vaccines can put together with food, drinks, and laboratory specimens, and the majority of the respondents were bothered by the vaccine potency if medicines and specimens are placed together. This revealed that respondents had a better understanding of what is happening if vaccines are kept in none dedicated refrigerator but 78.7% of the health professionals had good knowledge of cold chain management (Azira *et al*, 2013).

A study conducted in Saudi Arabia, Dammam at Government health facilities (GHF) and private health facilities(PHF) revealed that the knowledge of healthcare workers in vaccine storage procedures when the equipment failure or power off was 100% for government health facilities and 40% for the private health-care facilities (Mugharbel *et al*., 2009).

A study conducted in Lagos, Nigeria revealed that 95% of health workers had poor knowledge of VVM status (Bankole *et al*, 2010); and a study in South India also revealed that 39.5% of the health professionals did not know how to monitor vaccine temperature and also 81.6% of the health workers did not know about shake test and its importance (Rao *et al.*, 2012).

A study conducted in primary healthcare facilities in Edo State Nigeria revealed that a higher proportion of respondents (64.0%) had poor knowledge of cold chain management. But the majority of the respondents (93.2%) had a positive attitude (Ogboghodo *et al*., 2018). on the contrary findings from a study carried out in Kelantan, Malaysia over 75% of respondents had a negative attitude toward the cold chain(Azira *et al*., 2013).

2.2.3 Challenges in Cold Chain Management Practice

Studies conducted in India focused on the relationship between the VVM and the cold chain infrastructure and 98.8% of the facilities they visited showed VVMs of stage one and reconstitution time was not documented on the vaccine vial (Samant *et al*., 2007).

According to a study in Dammam, Saudi around 91% of government health facilities and 80% of private healthcare rooms kept the standards, and 40% of the private health facilities and 90.9% of the government health facilities, the temperature of the refrigerator was within the normal temperature range (Mugharbel *et al*., 2009).

2.2.4 Ethiopian Perspective on Vaccine Management Practice

In Ethiopia, cold chain equipment inventory was carried out at the national level. The objective of the inventory was to identify the status of cold chain equipment in the public health facilities in the country. Some of the problems identified from the assessment included inadequate and aging cold chain equipment, lack of maintenance system at all levels, lack of spare parts, and the use of several makes of refrigerators and freezers. Besides, the report revealed that 35% of equipment was not functional, and also 83% of the functional equipment's been greater than 10 years age and more than 14% of the functional equipment were sub-standard equipment and from nationally available refrigerators and freezers, 38% at the health facility level and 36% at woreda & region level were not functional (FMOH, 2013).

A study done in central Ethiopia showed that 21.6% of health workers know how to use conditioned ice packs for proper vaccine management during transportation (Roggie *et al.*, 2013). A study conducted in Hadya public health facilities on cold chain management disclosed that seventy-three of health centers immunogenic storage within the icebox was inappropriate, Inadequate air circulation between immunogenic boxes present within the incorrect arrangement of the icebox, and absence of ice pack in the refrigerators were the most important reasons for improper storage of vaccine (Berhane and Demissie, 2000).

Assessments had done in the Oromiya, SNNP, and Amhara regions showed that, among 116 visited facilities, only 19% had functional refrigerators. And complete temperature recording of the last month was observed only in 59.1% of facilities (Lakew *et al*., 2017).

A study conducted to assess the cold chain management follow at public health facilities in the North Shoa Zone Ethiopian Region showed that 81.7% (n=49) out of sixty facilities monitored

the cold chain on a twice-daily basis at the time of visit. Taking the last six-month temperature observation standing of the facilities, 51.7% (n=31) of the facilities had a complete set of twice daily manual temperature observation charts. In 38.3% (n=23) of the facilities, one or additional refrigerators were nonfunctional (Solomon, 2018).

In Nekemit city the study was conducted in government health facilities, the result showed that 44% of the respondents didn't store the vaccine as per the national standards. therefore, these affect the standard of temperature-sensitive medicines and the risk for public health (Fekadu *et al*., 2018). However, once it happened, 57.7% still store within the cold chain for future use and 19.7% of the health facilities stop mistreatment and recorded within the book for cold chain medicines discarded because of incorrect storage temperature. They also responded that 62.9% was a record of cold chain medicines discarded due to incorrect storage temperature (Fekadu *et al*., 2018).

2.3. Conceptual Framework

WHO recommends the range of temperature for storing and transporting vaccines and diluent should be based on data supplied by the manufacturer. Each vaccine has its specific storage requirements so it is extremely important to know how long, and at what temperature each vaccine should be handled as they are delicate biological substances that can become less effective or destroyed if they are not stored and transported properly. The cold chain has three main components: transport and storage equipment, trained personnel, and efficient or effective management procedures. The researcher was assessed vaccine management practice, basically the key operations such as training, supportive supervision, profession, educational background, years of service, and age of vaccine providers. This conceptual framework is all of these basic activities are performed well, it contributes to ensuring good knowledge and attitude.

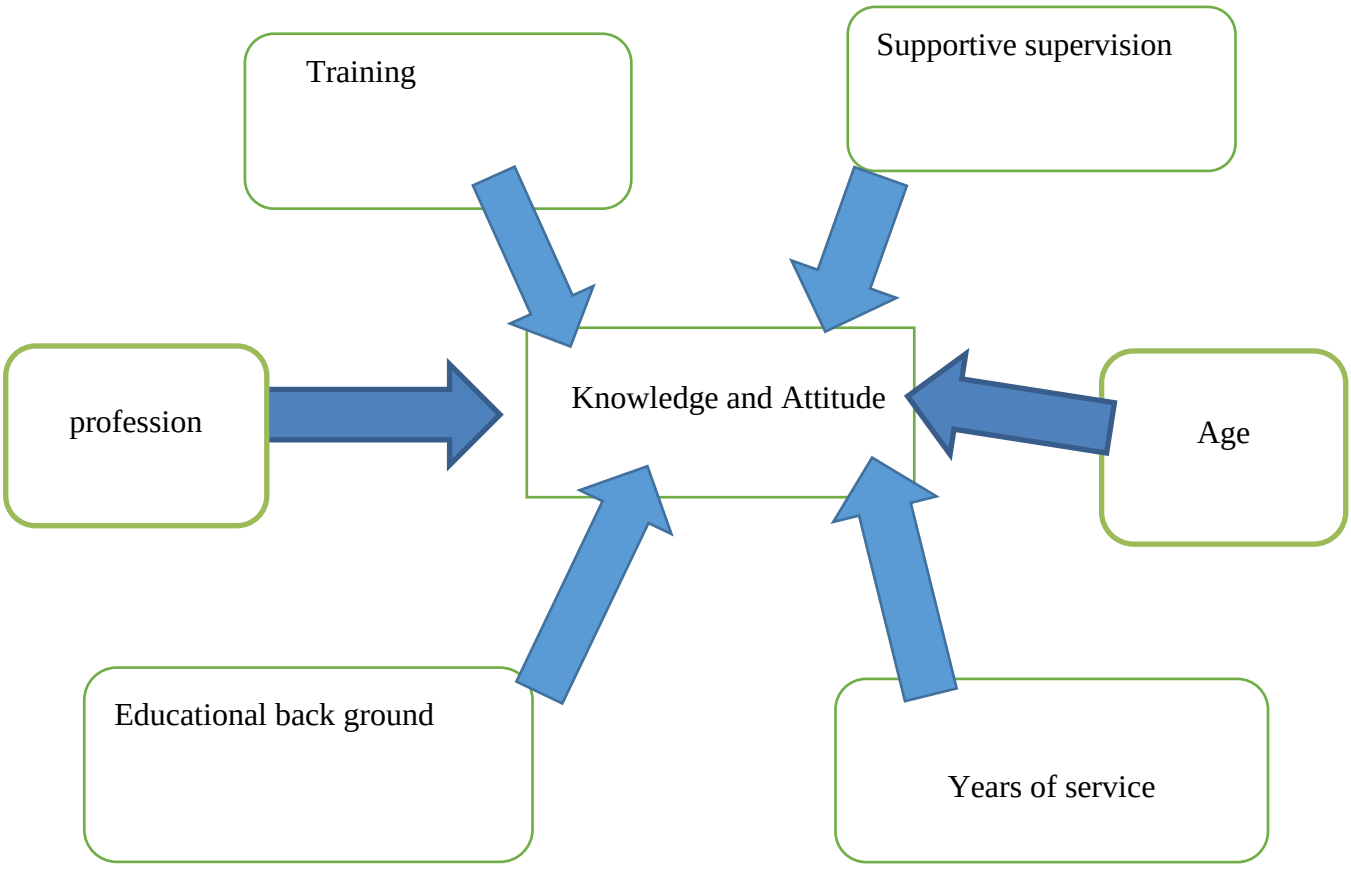

Figure 1: Conceptual framework

Adopted from Vaccine Management Guideline (WHO, 2005)

3. Objective

3.1. General Objective

- Assessment of vaccine provider's knowledge, and attitude, and private health facilities compliance with World Health Organization requirement of vaccine management practice, Addis Ababa, Ethiopia.

3.2. Specific Objectives

- To assess the knowledge of vaccine providers on vaccine management at the private health facilities in Addis Ababa City Administration.
- To assess the attitude of vaccine providers on vaccine management at the private health facilities in Addis Ababa City Administration.
- To assess the practice of private health facilities on vaccine management in Addis Ababa, City Administration.

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4. Method

4.1. The Study Area and Period

The study was conducted at selected private health facilities in Addis Ababa City Administration. Addis Ababa is the capital city of Ethiopia and covers an area of 540 km2. The Addis Ababa city population was projected to be 3.7 million by 2019 (CSA, 2013).

The city is, administratively divided into 10 sub-cities at the time of the data collection. There are 11 public hospitals, 98 public health centers, 53 private health facilities(18 hospitals and 35 MCH centers), and five NGO health facilities that provide immunization services. The private health facilities get the vaccine products from their catchment sub-cities, and Addis Ababa City Administration Health Bureau (AACAHB) and sub-cities monitor and regulate private health facilities vaccine management practices (City Government of Addis Ababa Health Bureau, 2018). The study was conducted from March to July 2020.

4.2. Study Design

A facility-based descriptive cross-sectional design using a structured observation checklist and self-administered questionnaire was followed in the study to Assessment of vaccine provider's knowledge, and attitude, and private health facilities' compliance with World Health Organization requirements of vaccine management practice, Addis Ababa, City Administration.

4.3. Source Population.

The source of the population for this study was private health facilities and health professionals who serve in the private health facilities in the Addis Ababa city administration.

4.4. Study Population.

The study population was the private health facilities that have been rendering immunization services and all health workers who have been administering vaccination services in the same facilities and fulfilling the eligibility criteria.

4.5. Eligibility Criteria

The following inclusion and exclusion criteria were applied in this study.

Inclusion Criteria:

- ✓ Private health facilities that provide immunization services for at least one year
- ✓ Health-care workers involved in immunization services more than one year elsewhere.

Exclusion Criteria:

- ✓ Private health facilities that were not operational at the time of data collection.
- ✓ Health-care workers who served for less than one year elsewhere.

4.6. Sampling Size Determination

To generate representative samples and a more realistic sample; the margin of error and confidence level for a logistic indicator assessment tool (LIAT) survey were set at 20 percent (+/-10 percent) and 90 percent, respectively (USAID, 2011).

The general formula for calculating sample size is:

$n = t^2 * p(1-p) / m^2$

n = required sample size

t = the confidence interval (at 90% t = 1.64)

p = estimated prevalence or the proportion of health facilities compliance with the WHO requirements of vaccine management practice(0.5). Since there was no similar study done in the area, prevalence is unknown. Therefore, P=0.5 was used.

m = margin of error 10%

$$n = t^2 * p(1-p) / m^2 = \frac{(1.64*1.64*0.5*0.5)}{(0.1*0.1)} = \frac{0.6724}{0.01} = 67.23 \approx 67$$

Where there is a predetermined population the sample size generated from the above equation needs to be multiplied by the Finite Population Correction (FPC) factor. Therefore to calculate the adjusted new sample size formula can be expressed as:

$$\text{New } \mathbf{n} = \frac{\boldsymbol{n}}{\mathbf{1} + [\frac{(\boldsymbol{n}-\mathbf{1})}{\boldsymbol{N}}]}$$

Where:

New n = the adjusted new sample size

N = the population size

n = the sample size

The final sample, New n = $\frac{67}{1+[\frac{(67-1)}{53}]} \approx$ **29.91=30**

4.7. Sampling Technique

Stratified random sampling was a useful method for data collection because the population was heterogeneous by facility types (Hospitals and MCH centers). Once the stratification and the sample size had been selected, the final step was to select the sample of facilities to be assessed from the list frame. The simplest sampling strategy was to use proportional allocation, in which the same sampling fraction was used for each stratum. There were 53 private health facilities (18 hospitals and 35 MCH centers) that provided vaccination services in Addis Ababa, and the sample size was 30, then 30/53= 57% of facilities were selected from each stratum. Therefore 10 hospitals from 18 and 20 from 35 MCH centers were selected by a simple random (lottery) method from each stratum. Thirty-four vaccine providers or immunization focal persons in the selected private health facilities that offer immunization services or who have vaccine management responsibility were included in the study.

4.8. Data Collection Process

The study utilized primary sources of data collection. The primary data were collected through self-administered questionnaires and structured observation- checklists. The profession of data collectors was nursing and health officer who worked in public health facilities. They had a minimum of 2 years of experience in their profession. Data collection was done using the above health professionals after explaining the purpose of the study well and telling as the confidentiality of the study will be kept secret. Supervisors were given the duties of checking for completeness and facilitating the fieldwork. The investigator was coordinating the daily activities of data collectors and supervisors.

4.9. Data Collection Instrument

The data collection instrument was a structured self-administered questionnaire and an observation checklist that was adapted from the WHO guidelines and other previous kinds of literature that did directly on the topic and related topics. The data was collected in two ways. The first way was a structured observational checklist as a means of recording the researcher's observation. The second way uses a self-administrative questionnaire which was developed

through careful review of the existing literature and following the WHO effective cold chain vaccine management guideline. The self-administered questionnaire consisted of 5 sections. Section I describes the information of the socio-demographic characteristics of the study participants, Section II describes the information on the study participants knowledge of vaccine management, Section III consisted of questions that assessed respondents' attitude toward vaccine management, Section IV, consisted of questions that assessed respondents' training on vaccine management and Section V consisted of questions that assessed barriers to effective vaccine management in the health facilities. The observational checklist was used to collect information regarding the availability of standard vaccine management equipment and EPI guidelines, the vaccine and diluent storage and handling, proper utilization of equipment, and maintenance of equipment VVM utilization, MDVP, and vaccine stock management by observing the document and reports. The structured self-administrative questionnaire and structured observation checklists were adapted from the WHO vaccine management assessment guideline (WHO, 2005) to collect quantitative data (see Annexes II and Annex III).

4.10. Data Analysis

Data entry and cleaning were done by a data entry clerk and the principal investigator. The data obtained from sample facilities were analyzed according to the objective of the study. To ensure completeness and consistency, data editing, and coding was carried out by the principal investigator before being entered into the analyzing software. Finally, the data obtained through the data collection instrument was entered and analyzed quantitatively using excel 2007 and SPSS version 20.

Knowledge of vaccine providers was assessed using a total of 13 questions. For each question, a score of 1 was an award for a correct answer and 0 for a wrong answer. The full knowledge score for every respondent was converted to percentages. Scores below 80.0% were categorized as poor knowledge and scores that were 80.0% and above were categorized as good knowledge.

The attitude of vaccine providers toward cold chain management was assessed using a total of 13 questions on a 3-point Likert scale. The positive response to a question was given a score of 1 while the negative response to a question a score of 0. The total attitude scores for each respondent were converted to percentages.

Test of associations of the variables was accomplished by using Chi-squared or the Fishers' Exact test where appropriate tests to determine the significant predictors of the sociodemographic variables of respondents with knowledge and attitude towards vaccine cold chain management. Statistical method using binary logistic regression was applied using the 'enter approach' to further determine the numerous predictors of the knowledge and attitude towards cold chain management and control for confounders. The statistical measure for the analysis was the adjusted odds ratio (OR) and 95% confidence interval (CI). The level of significance was set at $P < 0.05$ for all statistical associations of the variables. The study result was presented by frequency and percentage in tables and graphs whichever appropriate.

4.11. Data Quality Assurance

The questionnaire and the observation checklist for the data collection were standard because it was adapted from the WHO effective vaccine management assessment guidelines (WHO, 2005). One day of training was given to all data collectors by the principal investigator (PI) about the study procedures, source of data, and how to collect the data by observation before data collection. The PI has taken the basic cold chain management training. The PI has supervised the data collection process and has reviewed the completed questionnaires to clarify any data discrepancies

4.12. Operational Definitions

Cold Chain Monitors Devices: Are devices that monitor environmental conditions throughout the transport, storage, and handling of vaccines and diluents. These are single-use irreversible indicators that show once a temperature excursion has occurred higher than or below the recommended+2.0ºC to +8.0ºC.

Domestic refrigerator (household refrigerator): is an appliance that is used for the short-term preservation of food products in the home utilizing refrigeration.

Good attitude: -given for interviewee who answered at least 80% of attitude assessments question positively.

Good knowledge: -those who answered greater than 80% of knowledge assessment questions correctly.

Good practice of vaccine management:-effective vaccine management initiative provides materials and tools needed to monitor and assess vaccine cold chain performance.

Immunization: is that the method whereby someone is producing immune or proof against an associate in communicable disease, generally by the administration of vaccines.

Negative attitude: given for interviewee who answered less than 80% of attitude assessments question positively.

Poor knowledge: -those who answered less than 80% of knowledge assessment questions correctly.

Proper refrigerator storage: A refrigerator with adequate air circulation between the vaccine and vaccine is kept only on the refrigerator shelves and not in the door or bottom drawer, and no food or drink is stored in the refrigerator.

Standard vaccine refrigerator(s): an appliance that must be suitable for vaccine storage, capable of maintaining the required temperature range year-round, and have space to accommodate maximum inventory without crowding.

Vaccine Vial Monitors (VVMs): square measure tiny stickers that are attached to vaccine vials and alter color when the vaccine is exposed to heat

Vaccine: This is a biological preparation that improves immunity to the selected disease.

4.13. Ethical Considerations

Before commencing data collection, ethical clearance was obtained from the Ethical Review Committee of the School of Pharmacy, Addis Ababa University. An official letter of permission was taken from the Ethical Review Committee and given to Addis Ababa City Administrative Health Bureau. Then, the selected health facilities were communicated with letters from the Addis Ababa Health Bureau. Permission was taken from the responsible authorities of the health facilities. The study participants were informed about the aim of the study and written consent was obtained from the study participants. Confidentiality of the information taken was assured, the name and address of the health facilities, and confidentiality and privacy of the respondents were maintained by omitting the name of the respondents during the data collection procedure.

5. Results

A total of 30 health facilities; 10 (33.3%) Hospitals and 20(67.7%) MCH centers were included in this study. Self-administered questionnaires were administered to assess knowledge, attitude, and practice on vaccine management from vaccination service providers and immunization focal persons at the private health facilities in Addis Ababa. During observation, documents, manuals, recording, and reporting tools were reviewed on vaccine management practice in the private health facilities, and the results organized as follows:

5.1. Vaccine Providers Characteristics

A total of 34 respondents participated in the study as shown in Table 1. From the total respondents, the majority (41.7%) were 20-30 years old. Twenty-one (61.8%) had a diploma level of education. Among the vaccine providers included in the study, the majority were clinical nurses. The majority of the study participants had received training in vaccine cold chain management and were supervised by different and higher-level health organizations in the health system.

Table 1: Sociodemographic characteristics of vaccine providers in, Addis Ababa, 2020(n=34)

Variable	Number	(%)
Age group (years)		
20 -30 years.	16	47.1
31- 40 years.	12	35.3
41- 50 years	4	11.8
Above 50 years	2	5.8
Sex		
Males	4	11.8
Females	30	88.2
Educational back ground		
Diploma	21	61.8
Degree	12	35.3
Masters	1	2.9
Years of experience		

2 -5 years	20	58.9
6-10 years	8	23.5
> 10 years	6	17.6
Professions		
Diploma nurse	17	50
BSC nurse	12	35.3
Midwifery	5	14.7
Training in vaccine management		
Yes	28	82.4
No	6	17.6
Regular supportive supervision for the HF		
Yes	28	82.4
No	6	17.6

5.2. Knowledge of Vaccine Providers

Respondents were asked about the recommended temperature range for vaccine storage in health facilities and the majority (88.2%) responded correctly described storage temperature ranges to the different antigens available in the country's immunization program. The majority(97.1%) of the respondents correctly described the WHO multi-dose vial policy and 31(91.2%) the frequency of the daily temperature monitoring and recording. About, half (47.1%) of the respondents did not know the temperature range for most vaccines stored in freezers. The higher proportion(79.4%) of the study participants had an overall good knowledge of vaccine cold chain management [Table 2].

Table 2: Knowledge of vaccine providers toward vaccine management in private Health Facilities, Addis Ababa, 2020(n=34)

Variable	know (%)	Not know(%)
Temperature range for vaccines stored in refrigerators	30(88.2)	4(11.8)
Temperature range for vaccines stored in freezers	18(52.9)	16(47.1)
How to determine vaccines' stock quantity at the facility level	21(61.8)	13(38.2)
Freeze sensitive vaccines	28(82.4)	6(17.6)
Heat sensitive vaccines	20(58.8)	14(41.2)
The type of vaccine recommended being stored in the freezer room at the central level	22(67.4)	12(32.6)
Frequency of monitoring and recording of refrigerator temperature	31(91.2)	3(8.8)
A condition requiring "shake test" and its importance	32(94.1)	2(5.9)
Vaccine Vial Monitor (VVM) policy	33(97.1)	1(2.9)
WHO multi-dose vial policy	33(97.1)	1(2.9)
First Expire First Out (FEFO) principle	31(91.2)	3(8.8)
Vaccine transport requirements /chilled water or conditioned ice pack, & packaging	29(85.3)	5(14.7)
Contingency plan/actions when power off or cold chain equipment break down	21(61.8)	13(38.2)
Overall knowledge score	27(79.4%)	7(20.6%)

5.3. Sociodemographic Characteristics of Variable and Knowledge

Knowledge of vaccine and cold chain management was higher 14(70%) among respondents that had been administering vaccine for less than five years than those providing for more than ten years. However the association between the service year of vaccine providers and knowledge was not statistically significant (P =0.056, CI = 0.977–6.898) [Table 4]. Study participants who had received training 24(85.75%) had good knowledge of cold chain management but those who had no training, only (16.6%) of the study participants had good knowledge of cold chain management. The association between training and knowledge of the vaccine cold chain was

statistically significant (P = 0.001) [Table 3]. Having training of the vaccine providers on vaccine cold chain management increased having of good knowledge of vaccine cold chain management by an OR of 3.833, and this was statistically significant (P =0.042, CI = 1.072- 15.145) [Table 4]. Knowledge of vaccine and cold chain management was higher among respondents whose health facility received supportive supervision 22(78.5%). The association between supportive supervision and knowledge of vaccine and cold chain management was statistically significant (P = 0.003) [Table 3]. Having supportive supervision at HF increased having of good knowledge of cold chain management by an OR of 4.431, and this was statistically significant (P =0.026, CI = 1.304–16.898) [Table 4].

Table 3: Sociodemographic characteristics of variable and knowledge toward vaccine cold chain management in Private Health Facilities, Addis Ababa, 2020(n=34)

Variable	know (%)	Not know(%)	Chi-squared	P
Age (years)				
20 -29 years.	10(62.5)	6(37.5)	7.296	0.294
30- 39 years.	11(91.7)	1(8.3)		
40- 49 years	3(75.0)	1(25.0)		
Above 49 years	1(50.0)	1(50.0)		
Sex				
Male	3(75.0)	1(25.0)	1.632	0.201
Female	21(70.0)	9(30.0)		
Educational background				
Diploma	11(52.4)	10(47.6)	3.766	0.152
Degree	10(83.3)	2(16.7)		
Masters	1(100)	0		
Years of experience				
2-5 years	14(70.0)	6 (30.0)	6.335	0.052
6-10 years	6 (75.0)	2(25.0)		
> 10 years	1 (16.7)	5(83.3)		
Professions				

Diploma nurse	13(76.4)	4 (23.6)	2.649	0.266
BSC nurse	9 (75.0)	3 (25.0)		
Midwifery	2 (33.3)	3 (66.7)		
Training on vaccine management				
Yes	24(85.7)	4 (14.3)	12.103	0.001
No	1(16.6)	5 (83.4)		
Supportive Supervision				
Yes	22(78.5)	6(21.5)	8.652	0.003
No	1(16.6)	5(83.4)		

Table 4: Logistic regression model for determinants of knowledge of vaccine cold chain management in Private Health Facilities, Addis Ababa, 2020(n=34)

Predictors	regression co-efficient	OR	95% CI for OR		P
			Lower	Upper	
Age	0.345	0.998	0.914	5.296	0.069
Sex	0.281	1.001	0.117	14.089	0.063
Education	1.346	0.822	0.932	15.831	0.062
Years of service	0.954	0.929	0.977	6.898	0.056
Profession	0.672	1.052	0.704	5.443	0.198
Training					
Yes		1			
No	1.992	3.833	1.072	15.145	0.042
Supportive supervision					
Yes		1			
No	2.219	4.431	1.304	16.898	0.026

5.4. Attitude of Vaccine Provides

As shown in Table 5, most 32 (94.2 %) of respondents agreed to the use of adequate ice packs in the cold box to maintain the standard. temperature. Half of (47.1%) of the respondents disagree with the advice of limiting the opening of the refrigerator to less than 3 times per day. Fourteen (41.2%) of the respondents did not agree that vaccines are safe when managed by properly-trained individuals and 10(29.4%) of the respondents' attitudes agreed to store vaccines with food, drinks, and laboratory specimen will damage vaccines. The higher (88.2%) proportion of the study participant has a good or positive attitude regarding vaccine potency would be affected

if medicine and laboratory specimen is put together in the refrigerator. The majority (76.5%) of the study participants have a positive attitude to the vaccine cold chain management.

Table 5: Attitude of vaccine providers toward vaccine management in Private Health Facilities, Addis Ababa, 2020 (n=34)

Variable	Disagree		Neutral		Agree	
	Frequency	Percent (%)	Frequency	Percent (%)	Frequency	Percent (%)
Adequate ice packs in the cold box to maintain the optimal temperature	2	5.8	0	0	32	94.2
Bother if the refrigerator is opened > 3 times per day	16	47.1	0	0	18	52.9
'OPEN WHEN NEEDED' should be label on refrigerator	9	26.5	3	8.8	22	64.7
The vaccine should be stored in a dedicated refrigerator	1	2.9	1	2.9	32	94.2
Shake test is important to determine vaccines potency	6	17.6	0	0	28	82.4
Bother to record the temperature twice day	5	14.7	1	2.9	28	82.4
A special thermometer is used to measure internal refrigerator temperature	8	23.5	0	0	26	76.5
The temperature should be read without taking out the thermometer from the refrigerator	8	23.5	1	2.9	25	73.6
Vaccines should be managed by vaccine cold chain management trained individuals	13	38.3	1	2.9	20	58.8
Putting vaccines with food, drinks, and laboratory specimen will damage vaccines	9	26.5	1	2.9	24	70.6
Vaccine management system affected by harsh weather	11	32.4	0	0	23	67.6
The temperature monitoring device is essential for the temperature monitoring of vaccines.	5	14.7	1	2.9	28	82.4
Concerned regarding vaccine potency if medicine and specimen are put together in the refrigerator	4	11.8	0	0	30	88.2
Over attitude score					26	76.5

5.5. Sociodemographic Variable and Attitude

This study showed that a service provider who has a Master's degree and a Bachelors's degree had a higher positive attitude toward cold chain management (100%), and (91.7%) respectively.

The association between training and attitude toward the vaccine cold chain management was statistically significant (P = 0.006). Having training of the vaccine providers on vaccine cold chain management increased having of the positive attitude of vaccine providers on vaccine cold chain management by an OR of 6.230, and this was statistically significant (P =0.019, CI = 0.897- 14.145) [Table 7). The association between supportive supervision to the health facilities and providers' attitudes towards vaccine cold chain management was statistically significant (P = 0.048)[Table 6]. Having supportive supervision at HF increased having the positive attitude of vaccine providers on vaccine cold chain management by an OR of 4.167, and this was statistically significant (P =0.043, CI = 2.099-12.715) [Table 7].

Table 6: Sociodemographic variable and attitude toward vaccine cold chain management in Private Health facilities, Addis Ababa, 2020(n=34)

Variable	Positive(%)	Negative(%)	Chi-squared	P
Age group (years)				
20 -29 years.	13(81.2)	3(18.8)	1.252	0.741
30- 39 years.	10 (83.3)	2(16.7)		
40- 50 years	3 (75)	1(25)		
Above 50 years	1(50.0)	1(50.0)		
Sex				
Male	1 (25.0)	3(75.0)	2.141	0.143
Female	19(63.3)	11(36.7)		
Level of educational				
Diploma	10 (47.6)	11(52.4)	7.050	0.029
Bachelor degree	11 (91.7)	1(8.3)		
Master degree	1(100)	0		
Years of experience				
2-5 years	16 (80.0)	4(20.0)	2.146	0.062
6-10 years	6 (75.0)	2(25.0)		

> 10 years	3 50.0)	3(50.0)		
Professions				
Diploma nurse	14(82.4)	3(17.6)	7.209	0.055
BSC nurse	9(75.0)	3(25.0)		
Midwifery	1(20.0)	4(80.0)		
Training on vaccine management				
Yes	24(85.7)	4(14.3)	7.535	0.006
No	2(33.3)	4(66.7)		
Supportive Supervision at HF				
Yes	21(75.00)	7(25.0)	3.920	0.048
No	2(33.3)	4(66.7)		

Table 7: Logistic regression model for determinants of attitude towards vaccine cold chain management in Private Health facilities, Addis Ababa, 2020(n=34)

Predictors	regression coefficient	OR	95% CI for OR		P
			Lower	Upper	
Age	0.030	1.011	0.414	2.173	0.0942
Sex	0.520	1.182	0.842	3.358	0.141
Education	1.091	0.988	0.774	11.464	0.113
Years of service					
>10 years		1			
<10 years	1.018	0.809	1.040	7.358	0.051
Profession	0.735	1.016	0.759	5.535	0.154
Training					
Yes		1			
No	1.423	6.230	0.897	14.145	0.019
Supportive supervision					
Yes		1			
No	1.792	4.167	2.099	12.715	0.043

5.6. Vaccine Management Training for Vaccine Providers

The majority (85.3%) of the respondents were trained on the vaccine and cold chain management; storing vaccines on correct storage temperature range, types of vaccines damaged by freezing and heat, and types of temperature monitoring devices. A majority (82.4%) of the respondents attended training on VVM reading, shake test, and arrangement of vaccines in

refrigerators, and freezers. On the other hand, (35.3%) of the respondents reported not having training on the proper storage of diluents [Table 8].

Table 8: Vaccine management training for vaccine providers in Private Health facilities, Addis Ababa, 2020 (n=34)

Training of Vaccine management on:	YES(%)	NO(%)
Correct storage temperature range of vaccines	29(85.3)	5(14.7)
Vaccines damaged by freezing	29(85.3)	5(14.7)
Vaccines damaged by heat	29(85.3)	5(14.7)
VVM reading	28(82.4)	6(17.6)
Shake test	28(82.4)	6(17.6)
Types of temperature monitoring devices	29(85.3)	5(14.7)
Storage of diluents	22(64.7)	12(35.3)
Arrangement of vaccines in refrigerators, and freezers	28(82.4)	6(17.6)
Cold box/vaccine carrier packing	27(79.4)	7(20.6)

5.7. Availability of Standard Cold Chain Equipment

Table 9 revealed the availability of cold chain equipment in each health facility. Concerning cold chain equipment, most (90%) of the health facilities have no WHO standard refrigerator.

The national guidelines recommend each health facility have a standard refrigerator to offer immunization services but only 3 (10%) facilities possessed standard cold chain equipment. Twenty-five (83.3%) facilities had adequate ice packs and 19 (63.3%) had enough and functional cold boxes and vaccine carriers in good condition. The majority (93.3%) of the health facilities had a functional backup generator and kerosene for at least 72 hours. Fifteen (50%) of the health facilities had spare parts for minor fridge maintenance.

Table 9: Availability of Cold chain Equipment in Private Health facilities, Addis Ababa, 2020 (n=30)

Variable	Available(%)	Notavailable(%)
WHO standard functional refrigerators in the facility	3(10.0)	27(90.0)
Available non functional refrigerators in the facility	6(20.0)	24(80.0)
A refrigerator monitoring device in available the facility	26(86.7)	4(13.3)
Sufficient icepack in the facility	25(83.3)	5(16.7)
Sufficient cold boxes and vaccine carriers	19(63.3)	11(36.7)
Availability of kerosene for a generator for at least 72 hours	28(93.3)	2(6.7)
Daily temperature recording chart availability	27(90.0)	3(10.0)
Availability of functional backup generator in the facility	28(93.3)	2(6.7)
Availability of spare parts for minor fridge maintenance	15(50.0)	15(50.0)

5.8. Availability of Personnel and EPI Guidelines

Most (76.7%) of the health facilities had policies, standard operation procedures, and guidelines for vaccine management and the majority (90%) of the health facilities had a daily temperature recording chart. Thirteen(43.3%) of the health facilities were not assigned personnel to monitor the vaccine cold chain during holidays and weekends. Most 21(70%)of the health facilities had trained personnel to maintenance broken refrigerators e [Table 10].

Table 10: Availability personnel& EPI Guidelines in Privat Health Facilities, Addis Ababa, 2020 (n=30)

Variable	Available)%)	Notavailable(%)
Policies, procedures, and guidelines for vaccine management	23(76.7)	7(23.3)
Daily temperature recording chart availability	27(90.0)	3(10.0)
Personnel assigned during holidays/weekends for cold chain follow up	17(56.7)	13(43.3)
Permanently assigned trained personnel for cold chain management	27(90.0	3(10.0)
Availability of trained personnel for monitor refrigerator maintenance	21(70.0)	9(30.0)

5.9. Vaccine Stock Management Practice

Out of the total 30 health facilities, half(50%) have a ledger book for vaccine registration, Of this onlyy13 (43.3%) of the health facilities correctly filled in the required information (quantity, dose, batch number, expiry date, and manufacturer), while 17(56.7%) of the health facilities' stock records were incomplete. The majority (90%) of the health facilities ordered vaccines by a designated person. The majority (83.3%) of facilities applied the FEFO principle [Table 11].

Table 11: Vaccine management practice in Private Health Facilities, Addis Ababa, 2020 (n=34)

Variable	Yes(%)	No(%)
Stock cards/ledger books for vaccines are kept.	15(50.0)	15(50.0)
Stock cards/leger books for vaccines are correctly filled in.	13(43.3)	17(56.7)
Vaccines checked either discrepancies, leakage, or damage before receiving.	18(60.0)	12(40.0)
Recording the date and time, vaccine types, brands, quantities, batch numbers, and expiry dates when received.	22(73.3)	8(26.7)
There are no times vaccines are out of stock.	21(70.0)	9(30.0)
Vaccines are ordered by a designated person	27(90.0)	3(10.0)
Vaccine stock is monitored before ordering	24(80.0)	6(20.0)
There is no shortage of needles, syringes, and sharps containers	26(86.7)	4(13.3)
There are more than four weeks of stock in the refrigerator.	22(73.3)	8(26.7)
First expired first out principle applies when using and packing vaccines	25(83.3)	5(16.7)

5.10. Vaccine Refrigerator and Cold Chain Management Practice

Most (90%) of the refrigerators found in the private health facilities were in working order. All (100%) health facilities were stored vaccines in the dedicated refrigerator. Most(60%) of the refrigerators were not adequate for current and future demand. In eighteen (60%) private health facilities, the refrigerator was not situated in a well-ventilated area. In most(83.3%) private health facilities vaccines were stored in the correct range of temperature (2 - 8ºC) all the time.

The majority (90%) of the health facilities had a refrigerator temperature recording chart to monitor vaccine storage and from which facilities 26(86.7%) of them were recording temperature charts twice daily. In half (50%) of the health facilities, the refrigerator was not correctly packed with air circulating between the vaccines. A higher 22(73.3%) proportion of the

health facilities placed a working temperature motoring device in the center of the refrigerator. About half(46.7%) private health facilities stored vaccines in the manufacturing packaging box with leaflets [Table 12]

Table 12: Vaccine Refrigerator and Cold Chain Management Practice in Private Health Facilities, Addis Ababa,2020(n=30)

Variable	Yes (%)	No (%)
The refrigerator is in working order.	27(90.0)	3(10.0)
A dedicated refrigerator is used for the storage of vaccines only.	30(100.0)	0(00.0)
The refrigerator is situated in a well-ventilated area, away from sunlight and heat.	12(40.0)	18(60.0)
The refrigerator type is correct or standard for vaccines.	3(10.0)	27(90.0)
The refrigerator is the right size to store adequate vaccines when the demand increases.	12(40.00	18(60.0)
Refrigerator temperature is in the correct range of (2 - 8ºC) all the time.	25(83.3)	5(16.7)
Deviations outside 2 - 8ºC have been documented and actions were taken	14(46.7)	16(53.3)
"Do not unplug the refrigerator" sign next to the refrigerator.	12(40.0)	18(60.0)
Vaccines and diluents are stored correctly	14(46.7)	16(53.3)
Food or cool drinks are stored in the same refrigerator that is used to store vaccines.	0	30(100)
The refrigerator is either lockable or stored in a locked room	17(56.7)	13(43.3)
Vaccines are not stored in the door, bottom drawer, or adjacent to the freezer.	34(100.0)	0
Availability of filled refrigerator temperature recording chart	27(90.0)	3(10.0)
The temperature recording chart is filled in twice daily	26(86.7)	4(13.3)
The electricity supply to the refrigerator is safe (switchless plugs,	25(83.3)	5(16.7)

cautionary notices are in place).		
Arrangements are in place in the event of a refrigerator or power failure	20(66.7)	10(33.3)
The refrigerator is correctly packed with air circulating between the vaccines.	15(50.0)	15(50.0)
Records of regular refrigerator servicing, defrosting, and cleaning	16(53.3)	14(46.7)
Working temperature motoring device placed in the center of the refrigerator.	22(73.3)	8(22.7)
No expired vaccines in the refrigerator.	25(83.3)	5(16.7)
Sticker on the door to remind staff to open the door only when necessary.	14(46.7)	16(53.3)
Vaccines are in their packaging box with an information leaflet.	16(53.3)	14(46.7)

7.11. Vaccine Cold box Management Practice

The study revealed that 53.3% of the facility had cold boxes in good condition and 46.7% of the facilities the cold boxes with poor condition or wrong sizes for the target. It was observed in 46.7% of the health facilities, the cold chain temperature range (+2 to 8 C) was not maintained and in only 53.3% of the health facilities, the cold box temperature was correctly maintained. [Table 13].

Table 13: Vaccine Cold box Management practice in Private Health Facilities, Addis Ababa, 2020(n=30)

Variable	Yes (%)	No (%)
Cold boxes in a good condition and right size	16(53.3)	14(46.7)
The working thermometer in the cold box	16(53.3)	14(46.7)
The temperature of the cold box between 2-8 degrees	16(53.3)	14(46.7)
Cold box pack correctly i.e. 6 ice packs	23(76.7)	7(23.3)
Ice packs conditioned before use	20(66.7)	10(33.3)

5.12. Multi-Dose Vial Policy Implementation Practices

Table 14 revealed 27(90%) of the private health facilities had been adopted & implemented the multi-dose vial policy and all (100%) of health facilities discarded reconstituted vials of freeze-dried vaccines after six hours of reconstitution or when sessions closed or whichever comes first. The majority(90%) of the health facilities kept open vials of liquid vaccines for the next immunization sessions or 28 days after opening whichever comes first and the majority(93.3%) of them were written date and time of opening on the vial. A higher (70%) proportion of the health facilities stored opened vials vaccine in a separate box.

Table 14: Multi-Dose Vial Policy Implementation practice in Private Health Facilities, Addis Ababa, 2020(n=30)

Variable	Yes (%)	No (%)
The multi-dose vial policy has been adopted & implemented by the facility	27(90.0)	3(10.0)
Opened vials of freeze-dried vaccines discarded within six hours of reconstitution	30(100)	0
Opened vials of liquid vaccines kept for the next immunization sessions or 28 days after opening	27(90.0)	3(10.0)
The date and time of opening is written on the vial	28(93.3)	2(6.7)
Opened vaccine vials are stored in a separate box	21(70.0)	9(30.0)

5.13. Effective VVM Implementation Practices

Table 15 revealed that the majority(66.7%) of the private health facilities had written instructions on the use of vaccine vial monitors (VVM), and make visible, to the vaccine providers. Most 26 (86.7%) of the vaccine providers know how to read VVM status. Seven (23.3%) vaccine providers did not prioritize VVM status changed to the 2nd stage over the first stage.

Table 15: Effective VVM Implementation practice in Private Health Facilities, Addis Ababa,2020(n=30)

Variable	Yes (%)	No (%)
Written instructions to the use of vaccine vial monitors (VVM), such as posters and stickers, available to health workers	20(66.7)	10(33.3)
Vaccine providers know how to read VVMs (Use sticker samples to check the knowledge)	26(86.7)	4(13.3)
Health workers use VVM status priority indicator for vaccine management purposes (e.g. does the health worker use Stage 2 vaccines first than stage 1)	23(76.7)	7(23.3)

5.14. Maintenance of Cold Chain Equipment Practice

This study revealed that most(60%) of the health facilities had no preventive maintenance schedule for refrigerators and 23(76.7%) of the health facilities had a budget for refrigerator maintenance. Fourteen (46.7%) of the health facilities faced spare parts shortage in the last six months [Table 16].

Table 16: Maintenance of Cold chain Equipment practice in Private Health Facilities, Addis Ababa, 20(n=30)

Variable	Yes (%)	No (%)
The preventive maintenance schedule for the refrigerator	18(60.0)	12(40.0)
During the past six months, had spare parts shortages	16(53.3)	14(46.7)
Budget available for refrigerator maintenance	23(76.7)	7(23.3)

5.15. Vaccine Stock Management Practice

The study revealed that most(66.7%) of the private health facilities recorded vaccine and diluent types on the ledger book. Most of the health facilities record; manufacturer, batch/lot numbers, and expiry dates when receiving. About half (47.7%) of the health facilities did not record VVM status when receiving. The majority (86.7%) of the health facilities have done physical counts during the last six months [Table 17].

Table 17: Vaccine Stock Management practice in Private Health Facilities, Addis Ababa, 2020(n=34)

Variable	Yes (%)	No (%)
Receipts vaccine and diluent quantity recorded	24(80.)	6(20.0)
Vaccine & diluent in doses recorded	23(76.7)	3(23.3)
Vaccine & diluent type recorded	20(66.7)	10(33.3)
Vaccine & diluent manufacturer recorded	18(60.0)	12(40.0)
Vaccine & diluent batch/lot numbers recorded	21(70.0)	9(30.0)
Vaccine & diluent expiry dates recorded	26(86.7)	4(13.3)
VVM status recorded during receiving	16(53.3)	14(47.7)
Vaccine requisition forms used for ordering and receiving	30(100)	0
Physical counts have been carried out and recorded conducted during the past six months	26(86.7)	4(13.3)

5.16. Barriers to Effective Vaccine Handling and Storage

The majority (88.2%) of the study participants had faced a lack of standard refrigerators for proper vaccine storage. Fourteen (41.1%) of service providers never took the vaccine and cold chain management training. A similar proportion (41.1%) of respondents reported as having received a vaccine which its' VVM status approached the discarding point (Figure 2).

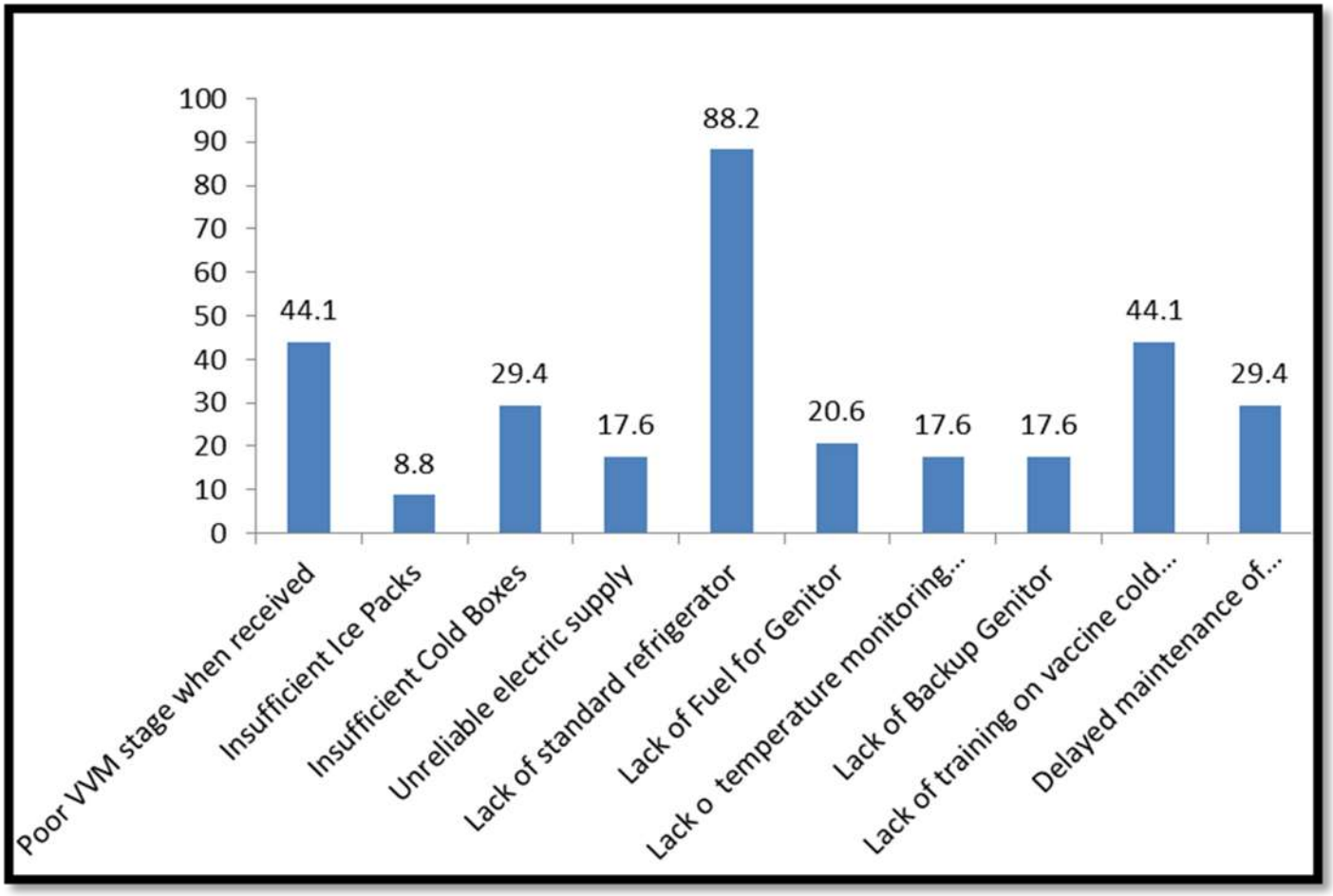

Figure 2: Barriers of Vaccine Cold Chain Management

6. Discussion

This study identified different gaps related to the vaccine cold chain management system such as poor knowledge of the vaccine providers, negative attitude of vaccine providers towards vaccine management, lack of WHO prequalified standard refrigerators, lack of basic and refrainment training on vaccine cold chain management, lack of supportive supervision and monitoring, poor vaccine stock recording and VVM status, lack of trained maintenance personnel, lack of spare parts and budget to maintain when the refrigerators broke or damage.

This study revealed that 20(58.8%), and 28(82.4%) of vaccine providers had good knowledge about which vaccines are most sensitive to heat, and to freeze respectively. CDC's guidelines indicated that by following few simple steps and implementing the best storage and handling practices, vaccine providers can ensure that children and their mothers could get the full benefit of vaccines they received (CDC, 2018). which is slightly different from the study conducted in health facilities in Addis Ababa and Mozambique 65.4% and 67% of respondents know which vaccines were freeze-sensitive respectively (Berhanu, 2009; Joao et al, 2007).

Of the total 34 vaccine providers included in the survey, 30(88.2%), and 32(94.1%) know the recommended range of temperature for vaccine storage and vaccines that need a shake test respectively. The poor knowledge about correct storage temperature range and shake test could even be expected to adversely affect the quality of vaccines administered and consequently, the substandard practice can crumple for vaccine-preventable diseases as evidenced in many other parts of the country outbreaks of vaccine-preventable diseases as are evidenced in many other parts of the country. This study showed comparatively better results compared to a study conducted in Benshangul-Gumuz showed; some 83.1% of respondents know the recommended temperature range for storage of vaccines and 52.3% could correctly identify vaccines that needed a shake test (Getachew *et al*., 2009).

Over 79% of respondents had good knowledge of overall, vaccine cold chain management. This can be contrasted with the study results done in Edo State Nigeria where most (60%) of respondents had no overall good knowledge of cold chain management (Ogboghodo, *et al.*, 2018). Poor knowledge in cold chain management may result in poor vaccine storage and cold chain monitoring practice. As respondents might not be able to recognize if the cold chain is

defective at any point and this could damage the vaccines. Hence, increase vaccine wastage is stated to be expensive (Mangeni, 2013).

Six (17%) of the study participant had not been supervised by different and higher-level health organizations in the health system. Supportive supervision was also found to be another strong determinant of better information on cold chain management. This might be attributed to the fact that supervisors within the course of conducting their jobs are better ready to identify areas, where the workers are deficient in knowledge requirements of cold chain management, could fill gaps, and ultimately providing better knowledge (Ogboghodo *et al*., 2018).

Overall, the majority of 26(76.5%) study participants in this study had a positive attitude toward cold chain management. This contrasted to findings from a study allotted in Kelantan, Malaysia, in which over three-quarters of respondents had a negative attitude toward cold chain management(Azira *et al.,* 2013). Health professional's attitude in their workplace has been found to directly affect their job performance, decisions, and turn-over (Saari and Judge, 2004). Specifically, the success of vaccine cold chain management has been stated to depend mainly on the attitude of the cold chain handlers. A positive attitude toward cold chain management would enable the respondents to process the knowledge and information they have on cold chain management with greater awareness, efficiency, and more appropriately translate into better practice.

Sixteen (47%) of the study participants were not bothered if the refrigerator is opened more than three times per day. In contrast to a study done in Malaysia, 75% of the study participants agreed to be bothered if the refrigerator is opened more than three times per day (Azira *et al.*, 2013). Opening the refrigerator more than three times per day affects the refrigerator's internal temperature and this causes vaccine loss of potency.

In the present study, 17.6% of study participants perceived that doing shake tests is not important in determining vaccine potency. However shake test has a high value in detecting freeze-damaged vaccines (WHO, 2012).

This assessment showed that, out of 30 private health facilities, only 3(10%) had WHO standard refrigerators, but most of the private health facilities had domestic refrigerators. WHO recommends stand-alone refrigerators or freezers and purpose-built refrigerators for storing vaccines, most domestic refrigerators are not fan-forced and have poor temperature recovery

after the door has been opened. Vaccine refrigerators closely control temperatures and can alarm if the temperature goes out of specifications. They also record minimum and maximum temperatures (WHO, 2012).

This study revealed that 28(93.3%) facilities had trained personnel, only17 (56.7%) were assigned during weekends and holidays, and 15(50%) of the private health facilities had spare parts for minor maintenance of refrigerators. Vaccines are delicate biological products that need to be continuously maintained within a recommended narrow range of temperatures (WHO, 2012). In this respect, the availability of trained personnel and spare parts at the health facility level are mandatory for regular follow-up and timely maintenance (WHO, 2014).

This study revealed that in 60% of the health facilities' vaccine refrigerators there was no “DO NOT UNPLUG” command on the refrigerator plug and on the fridge door stating “DO NOT OPEN VACCINE FRIDGE”. The National Vaccine Storage Guidelines (WHO, 2015) states that the vaccine fridge must be marked “DO NOT shut down OR DISCONNECT THE VACCINE FRIDGE”. Accidental disconnection of the electrical power can cause damage to vaccines by heat, especially if this goes unnoticed for an extended period. The rules further state that vaccine refrigerators must have the sign “ ON THE VACCINE REFRIGERATOR DON'T OPEN”. Reducing the number of times the fridge door is opened, helps to keep up the inner temperature of the fridge (Nelson *et al*., 2004). It's recommended that the command be bold so that visibility isn't an issue and hence the correct guidelines are often followed properly.

Most 27(90%) of the private health facilities had adopted and implemented the multi-dose vial policy in the facility and all 30(100%) of these health facilities had discarded opened vials of freeze-dried vaccines within six hours of reconstitution or after the session whichever comes first. Twenty-seven(90%) of health facilities kept open vials of liquid vaccines for the next immunization sessions or 28 days after opening. The EPI Cold Chain Standard Operating Procedures/ Manual states that for a multi vial dose policy, for example, measles and BCG vaccine, once opened must be discarded after six hours. For the liquid which is approved for MDVP, the dates and time must be recorded on the vaccine vial, and therefore the vaccine should be stored in an exceedingly separate box (WHO, 2014).

The results of this study revealed the majority of 18(60%) of the health facilities had no preventive maintenance schedule for refrigerators and 23.3% of the health facilities had no

budget for refrigerator maintenance. Fourteen (46.7%) of the health facilities faced a shortage of spare parts during the last six months. World health organization recommends that preventive maintenance of vaccine refrigerators is done before equipment failure because corrective maintenance should be minimal if preventive maintenance is effective (WHO, 2014).

Moreover, the finding showed that 20(66.7%) of the private health facilities recorded the vaccine and diluent types on ledger book when received and from which health facilities or vaccine store, vaccine & diluent by doses, manufacturer, batch/lot numbers, and expiry dates when receiving recorded were, 23(76.7%), 18(60%), and 26(86.7%) respectively. About half 14(47.7%) of the health facilities did not record VVM status when receiving vaccines. According to the vaccine cold chain management system (WHO, 2012), a stock recording system is a valuable tool in the management of vaccines, their storage movement, and use. The availability of reliable and quality stock is vital in availing of lifesaving vaccines and for informed decision-making processes at all levels of the supply chain system.

In general, the present study revealed that most of the private facilities' faced many challenges to implementing proper vaccine management practice with WHO standards these includes: the absence of standard refrigerators, poor VVM stage of the vaccine when received, lack of training, lack of budget for maintenance and delay in the maintenance of broken refrigerators. This might cause increased vaccine wastage, loss of vaccine potency, and costs.

7. Strengths and Limitations

The study used different data collection methods,(semi-structured self-administered questionnaire, and using the WHO vaccine management observation checklist). The data was collected by the health workers who attended the vaccine cold chain management training.

Due to logistic reasons the study was conducted only in private health facilities that provide immunization serves in the national capital city because of time and resource limitation, hence has a reduced statistical power; caution is required in generalizing these results. The cross-sectional design investigates prevalence and associations instead of causality. Thus, future research has to replicate these findings employing a large-scale sample size to generalize and using qualitative and quantitative study design producers at different levels of the health system.

8. Conclusion

The study has established different gaps related to the vaccine cold chain management system such as poor knowledge of the vaccine providers, negative attitude of vaccine providers towards vaccine management, and improper vaccine management practice of the private health facilities.

About half of the study participants did not know the temperature range for vaccines stored in the freezer room and also about 41% of the study participants did not know the type of high heat-sensitive vaccines. The poor knowledge about correct storage temperature range adversely affects the quality of vaccines administered and consequently, the substandard practice can crumple vaccine-preventable diseases.

About half of the study participants had a negative attitude or were not bothered if the refrigerator is opened more than three times per day. But the opening of the refrigerator more than three times per day affects the internal temperature of the refrigerator. A positive attitude toward cold chain management would enable the respondents to process the knowledge and information they have on cold chain management with greater awareness, efficiency, and more appropriately translate into better practice. Moreover, the knowledge and attitude of healthcare workers towards the vaccine cold chain management were significantly associated with the health workers' training and supportive supervision in health facilities.

Improper vaccine management practices affect the vaccine management systems. In most of the private facilities, the refrigerator was not situated in a well-ventilated area, the refrigerator was not the right size to store adequate vaccines, and the refrigerator was not correctly packed with air circulating between the vaccines. Only half of the health facilities had a ledger book for vaccine registration, of this only 43% of the health facilities correctly filled in the required information (quantity, dose, batch number, expiry date, and manufacturer). Most of the private facilities' had faced many challenges to implementing proper vaccine management practice with WHO standards these include: the absence of standard refrigerators, poor VVM stage of the vaccine when received, lack of training, lack of budget for maintenance, and delay in the maintenance of broken refrigerators. This might cause increased vaccine wastage, loss of vaccine potency, and costs of vaccine for the government and customer individual.

9. Recommendations

To maintain a safe and effective cold chain management, further efforts are needed for capacity-building activities for health professionals to address the knowledge gap, and attitude, improving vaccine management practice in all the health facilities. Therefore different stakeholders should do the following activities:

- All vaccine providers should have good knowledge and a positive attitude towards the vaccine management systems. Because Positive attitude toward cold chain management would enable the respondents to process the knowledge and information they have on cold chain management with greater awareness, efficiency, and more appropriately translate into better practice.
- Private health facilities should be improved vaccine management practices through proper recording of vaccine stock, proper temperature monitoring, and allocating budget for maintenance refrigerators and transportation.
- All private health facilities should avail or used WHO prequalified or standard refrigerators other than domestic refrigerators. Domestic refrigerators are unsuitable for vaccine storage because they are not designed to maintain the required temperature range.
- AACAHB, Sub-city health offices, and NGOs should:
    - ✓ Provide well-designed regular supportive supervision for the private health facilities.
    - ✓ Provide basic and refreshing training to address operational weaknesses

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ANNEXES:

Annexes 1: Introduction and Consent form

Verbal consent form

My name is Lake Alemayehu. Thank you for giving me the time to talk with you. I came from Addis Ababa university school of graduate studies school of pharmacy department of pharmaceutics and social pharmacy. We are asking questions of health workers /immunization officers/ such as you, throughout Addis Ababa, and collecting data for a master's thesis named "Assessment of vaccine provider's knowledge, and attitude, and private health facilities compliance with World Health Organization requirement of vaccine management practice, Addis Ababa, Ethiopia". This health facility has been chosen to be included in the study. If you agree to be interviewed, I will be asking you questions about your experience with immunization and the immunization supply chain. We are interested in finding out what health workers think about the immunization and immunization supply chain particularly vaccine wastage and factors associated with vaccine wastage. This information will be used to help know the quality immunization supply chain in Addis Ababa.

If you decide that you do not want to participate in the study or decide at any time in the future that you do not want to participate, it will not affect you in work in the health facility now or in the future. While the results of this study may be published, your privacy will be protected, and you will not be identified in any way. No one, including your supervisor, will know your answers. Your opinions-observation and experiences are important to us, so please be honest and truthful in answering our questions. Your answers will be confidential and secret. If you agree to be interviewed, we will go to a place where no one can hear us talking. If you are uncomfortable with a question, you do not have to answer it if you do not want it. It. you'll also stop the interview at any time. It will take about 30-45 minutes for us to complete the questionnaire. Do you have any questions about the study? If in the case should you have any questions about the study in the future, please feel free to contact Addis Ababa University and Addis Ababa Health Bureau or the research team leader Mr. Lake Alemayehu.

_____ _____

Signature of the person administering consent Date

Annexes 2: Self-Administered Questioner to immunization focal persons

I: Socio-demographic characteristics of the respondents

Please circle the option that best describes your response to the following statements

1	**Basic information**	Options
1.1	**Age group (years)**	
		1. 20-29 [ ]
		2. 30-39 [ ]
		3. 40-49 [ ]
		4. >50 [ ]
1.2	Sex	1. Male [ ]
		2. Female [ ]
1.3	Level of Education	
		1. Diploma [ ]
		2. Bachelor degree [ ]
		3. Master's degree [ ]
1.4	Profession	
		1. Diploma nurse [ ]
		2. BSc nurse [ ]
		3. Midwifery [ ]
1.5	Years of service	1. 1-5 years [ ]
		2. 6-10 years [ ]
		3. >10 years [ ]
1.6	Have taken vaccine management training?	1. Yes [ ]
		2. No [ ]
1.7	Have you got supportive supervision from AARHB/Sub-city quarterly	1. Yes [ ]
		2.No [ ]

II: Knowledge of Vaccine Providers on vaccine management practice

Please tick the choice that best describes your response to the subsequent statements:

2.1. What is the recommended temperature range for vaccines stored in refrigerators?

- □ −2˚C to +8˚C
- □ +2˚C to + 8˚C
- □ -15˚C to -25˚C
- □ 0˚C to +8˚C
- □ don't know

2.2. What is the recommended temperature range for most vaccines stored in freezers?

a) +2°C to +8 °C

b) -4 °C to -14 °C

c) -15 °C to -25 °C

d) -25 C° to -65°C

2.3. How do you determine your vaccines' stock quantity at your facility?

a) By determining only safety stock

b) By determining the only maximum stock level

c) By determining the only minimum stock level

d) By considering the safety stock, stock on hand minimum stock level and, maximum stock level

2.4. Which one is the highly freeze-sensitive vaccine?

a. OPV

b. Pentavalent

c. BCG

d. Measles

e. I don't know

2.5. Which vaccine is highly sensitive to heat?

a. IPV

b. Pentavalent

c. TT

d. OPV

e. I don’t know

2.6. Which vaccine is recommended to be stored in the freezer room at the central level?

a. IPV

b. OPV

c. Pentavalent

d. TT

e. I don’t know

2.7. The frequency of recording of refrigerator temperature is:

a. Two times per day

b. Three times per day

c. One time per day

d. Four times per day

e. I don’t know

2.8. Do you know about the shake test and its importance?

a. Yes,

b. No

If yes, explain what is shake test and its importance

_____

_____

_____

2.9. Do you know about Vaccine Vial Monitor (VVM) policy?

a. Yes,

b. No

If yes, explain what is Vaccine Vial Monitor (VVM) policy

_____

_____

_____

2.10. Do you know about the WHO Multi-Dose Vial Policy?

a. Yes,

b. No

If yes, explain what is the WHO Multi-Dose Vial Policy

_____

_____

_____

2.11. Do you know about First Expire First Out (FEFO) principle?

a. Yes,

b. No

If yes, please explain what is the FEFO principle

_____

_____

_____

2.12. Do you know about Vaccine transport requirements /chilled water or conditioned ice pack, and how packaging?

a. Yes,

b. No

If yes, explain what is conditioned ice pack, and how packaging

_____

_____

_____

2.13. Do you know about Contingency plans/actions when power or Cold chain equipment breaks

down?

a. Yes,

b. No

If yes, explain what is Contingency plans/actions

III: The attitude of Vaccine Providers on vaccine management practice

Each Likert scale represents the following rating:

1. Disagree; 2.Neutral; 3. Agree

Question: What is your level of agreement with the following statements that relate to the attitude of the health workers on vaccine management practice?

3	The attitude of health workers on vaccine management practice	1	2	3
3.1	You have to place an adequate number of ice packs in the cold box to maintain the optimal temperature			
3.2	You bother if the refrigerator is opened > 3 times per day			
3.3	You should put an 'OPEN WHEN NEEDED' label at every refrigerator door which stores vaccines			
3.4	You must store the vaccine in a dedicated refrigerator			
3.5	Doing a shake test is important to determine vaccine potency.			
3.6	You must record the temperature twice daily			
3.7	It is important to use a special thermometer to measure internal refrigerator temperature			
3.8	You should read the temperature without taking out the thermometer from the refrigerator			
3.9	Vaccines and diluents should be managed by cold chain management trained individuals			
3.10	Putting vaccine with Food, drinks, and laboratory specimen will damage vaccines potency			
3.11	Vaccine cold chain management system not affected by harsh weather & poor equipment			
3.12	The temperature monitoring device is an essential requirement for temperature monitoring of vaccines.			
3.13	You should be concerned regarding vaccine potency if medicine and specimen are put together in the refrigerator			

IV: Training of vaccine providers on vaccine management

Have you taken training in any of the following activities?

4	Training on:	Trained	Not trained
4.1	Correct vaccine storage temperature ranges		
4.2	Vaccine types highly damaged by freezing;		
4.3	Vaccine types highly damaged by heat		
4.4	VVM reading		
4.5	Shake test		
4.6	Temperature monitor reading & recording		
4.7	Storage of diluents		
4.8	Arrangement of vaccines in refrigerator compartments		
4.9	Cold box/vaccine carrier packing		

V: Barriers to effective vaccine management in the health facilities

Please tick the following barriers/challenges to effective vaccine handling and storage in your facility

5	**Barriers to effective vaccine management**	**YES**	**NO**
5.1	Poor VVM stage when received		
5.2	Insufficient Ice Packs		
5.3	Insufficient Cold Boxes		
5.4	Unreliable electric supply		
5.5	Lack of standard refrigerator		
5.6	Lack of Fuel for Genitor		
5.7	Lack o temperature monitoring devices		
5.8	Lack of Backup Genitor		
5.9	Lack of training on vaccine cold chain management		
5.10	Delayed maintenance of malfunctioning refrigerators		

Thank you for your kind participation!

Annex 3: Observational checklist of Vaccines management practices

Health facility code_____

Date of Visit:_____

1	**Availability of Cold Chain Equipment &EPI Guidelines**	**Available**	**Not available**
1.1	Available of functional WHO standards vaccine storage refrigerators		
1.2	Are available unfunctional refrigerators in the facility?		
1.3	Available refrigerator or monitoring device in the facility		
1.4	There is sufficient icepack in the facility		
1.5	There are sufficient cold boxes and vaccine carriers		
1.6	Available Policies and guidelines of vaccine management		
1.7	Available of kerosene for a generator for at least 72 hours		
1.8	Daily temperature recording chart availability		
1.9	Available of personnel assigned during holidays/weekend for cold chain follow up		
1.10	Available of permanently assigned personnel for cold chain management		
1.11	Available of the function generator in the facility		
1.12	Available spare parts for minor fridge maintenance		
1.13	Available trained personnel for monitor fridge maintenance		
1.14	Available of the budget for refrigerators maintenances		
2.	**Vaccine management**	**Yes**	**No**
2.1	Stock cards/ledger books for vaccines are kept.		
2.2	Stock cards/ ledger books for vaccines are correctly filled in.		
2.3	Vaccines are checked against the order for discrepancies and leakage or damage before receiving them.		
2.4	Procedures are followed for recording the date and time, vaccine types, brands, quantities, batch numbers, and expiry		

	dates when received.		
2.5	There are times vaccines out of stock.		
2.6	Vaccines are ordered by a designated person		
2.7	Vaccine stock is monitored before ordering		
2.8	There is a shortage of needles, syringes, and sharps containers		
2.9	There are more than four weeks of stock in the refrigerator.		
2.10	The first expired first out principle is applied when providing vaccines		
3	**Vaccine refrigerator**		
3.1	The refrigerator is in working order.		
3.2	A dedicated refrigerator is used for the storage of vaccines only.		
3.3	The refrigerator is situated in a well-ventilated area, away from sunlight and heat.		
3.4	The refrigerator type is standard or correct for vaccines.		
3.5	The refrigerator is the right size to store adequate vaccines when the demand increases.		
3.6	The refrigerator temperature is within the correct range of (2 - 8ºC) during observation.		
3.7	The responses to all deviations outside (2 - 8ºC) have been documented and the recommended actions are taken		
3.8	There is a “do not unplug the refrigerator” sign next to the refrigerator.		
3.9	Vaccines and diluents are stored correctly		
3.10	Food or cool drinks are stored in the same refrigerator that is used to store vaccines.		
3.11	The refrigerator is either lockable and locked or stored in a locked room		
3.12	Vaccines are stored in the door, bottom drawer, or adjacent to the freezer.		

3.13	A refrigerator temperature recording chart is present with a recording.		
3.14	The temperature chart is filled in twice daily		
3.15	Electricity supply to the refrigerator is safe examples- switchless plugs, cautionary notices are in place.		
3.16	The refrigerator is correctly packed with air circulating between the vaccines.		
3.17	There are records of regular refrigerator servicing, defrosting, and cleaning available.		
3.18	A working temperature motoring device is placed in the center of the refrigerator.		
3.19	There are no expired vaccines in the refrigerator.		
3.20	There is a sticker on the door to remind staff to open the door only when necessary.		
3.21	Vaccines are in their original packaging box and include the information leaflet.		
4	**Vaccine Cold box**		
4.1	Are the cold boxes in a good condition and the right size?		
4.2	Is there a working thermometer in the cold box?		
4.3	Is the temperature of the cold box between 2-8 degrees?		
4.4	Does the cold box pack correctly i.e. 6 ice packs?		
4.5	Do ice packs conditioned before use?		
5	**Multi-dose vial policy implementation practices**		
5.1	The multi-dose vial policy has been adopted and correctly implemented by the facility?		
5.2	Are opened vials of freeze-dried vaccines discarded within six hours of reconstitution?		
5.3	Are opened vials of liquid vaccines kept for the next immunization sessions or 28 days after opening?		
5.4	The date and time of opening is written on the vial		

5.5	Opened vaccine vials are stored in a separate box		
6	**Effective VVM use practices**		
6.1	Are written instructions on the use of vaccine vial monitors (VVM), such as posters and stickers, available to health workers		
6.2	Do storekeepers/health workers know how to read VVMs? (Use dummy VVMs and/or sticker samples to check the knowledge		
6.3	Do vaccine providers use VVM status for vaccine management purposes (e.g. do they use Stage 2 vaccines first)?		
7	**Maintenance of cold chain equipment practices**		
7.1	There is a preventive maintenance schedule for the refrigerator		
7.2	During the past six months, did a shortage of spare parts?		
7.3	Budget available for refrigerator maintenance		
8	**Stock management of vaccines**		
8.1	Are all receipts recorded and balances.		
8.2	Are vaccine & diluent quantities (in doses) recorded		
8.3	Are vaccine & diluent types recorded?		
8.4	Are vaccine & diluent manufacturer recorded		
8.5	Are vaccine & diluent batch/lot numbers recorded		
8.6	Are vaccine & diluent expiry dates recorded		
8.7	Is VVM status recorded during receiving		
8.8	Are vaccine requisition forms used for ordering and receiving?		
8.9	Have physical counts have been carried out and recorded conducted during the past six months?		

Annex 4: Ethical Clearance

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Addis Ababa University

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School of Pharmacy
Ethical Review Board

Date March 26, 2020

Ref. No. ERB/SOP/210/03/2020

To: **Lake Alemayehu**
School of Pharmacy

Re: **Ethical Clearance**

It is to be recalled that you submitted a study proposal entitled ***"Assessment of vaccine management practice knowledge and attitude of vaccine providers at private health facilities in Addis Ababa Ethiopia"*** for ethical approval by the School's Ethical Review Board (ERB). The Board thoroughly reviewed the proposal based on its operational guidelines and found it to fulfill all ethical requirements stipulated in the guidelines. This is, therefore, to inform you that the proposal is ethically approved for implementation.

With best regards,

Arebu Issa

Chairperson, ERB

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City Government of Addis Ababa Health Bureau

Ref.No. ጽ/ጽ/ጤ/9275/227
Date 2018/12

TO:

- Girum General Hospital
- Tekelhaimanot General Hospital
- Brass Hospital
- Hayat Hospital
- koria Hospital
- AbebechGobena MCH CenterArada
- Addis MCH Center
- Ananiya MCH Center
- Hemen MCH Center
- Abawoldetensay mothers a and childrens medium clinic
- ECA Clinic
- Betsega Mothers and Pdiatrics Center
- Hewan Obstetric and GynacologySpeciality Clinic
- BGM Mothers and Pediatrics Center
- Grace MCH Center
- Dinberua MCH Center
- Joy Obstatric And GyencologySpeciality Clinic
- Racy Health Center
- Ruth Health Center
- Naine MCH Specality Center
- TSIONObey-Gayne Special Clinic
- Care Gyne And Obste special Clinic
- Semah GYN and OBS Center
- Biham pediatric Speciality Clinic
- St Gebriel Hospital
- American Medical Center
- Yerer Primary Hospital
- Bethezatha General Hospital
- Betel No.2 MCH Hospital
- MigbareSenay General Hospital

Subject: Request to access Facilities to conduct approved research

The letter is to support **Lake Alemayehu** of **"Assessment of Vaccine Management Practice, Knowledge and Attitude of Vaccine Providers at Private Health Facilities, Addis Ababa, Ethiopia."** The study proposal was duly reviewed and approved by Addis Ababa Health Bureau IRB, and the principal investigator is informed with a copy of this letter to report any changes in the study procedures and submit an activity progress report to the Ethical Committee as required. Therefore we request the facility and staffs to provide support to the principal investigator.

With Regards

Ethical Clearance Committee

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Cc

- **Lake Alemayehu**
- **To Ethical Clearance Committee**
  Addis Ababa