ADDIS ABABA UNIVERSITY

SCHOOL OF PHARMACY

COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF PHARMACEUTICS AND SOCIAL PHARMACY

ASSESSMENT OF VACCINE WASTAGE AND CONTRIBUTING FACTORS IN SELECTED HEALTH CENTERS OF ADDIS ABABA, ETHIOPIA.

BY:

TESFAHUN TAWYE

August, 2020

ADDIS ABABA, ETHIOPIA

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A THESIS SUBMITTED TO THE SCHOOL OF PHARMACY OF ADDIS ABABA UNIVERSITY IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF SCIENCE IN HEALTH SUPPLY CHAIN MANAGEMENT.

ADVISOR: BRUCK MESSELE (B.PHARM, MSC, PhD)

: TARIKU BERHANU (PhD)

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This is to certify that the thesis prepared by Tesfahun Tawye Genber, entitled: assessment of vaccine wastage and its contributing factors in selected health centers of Addis Ababa, Ethiopia and submitted in partial fulfillment of the requirements for Master of Science in health supply chain management and meets the accepted standards with respect to originality and quality.

Signed by:

Advisor: Bruck Messele (PhD) Signature _____Date _____

Advisor: Tariku Berhanu (PhD) Signature _____Date _____

Examiner: Michael Dejene (PhD) Signature _____Date _____

Examiner: Tesfaye Tsigue (MSC) Signature _____Date _____

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Chairman of Department

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IV. **Acronyms**

AACAHB	Addis Ababa city administration health bureau
AAU	Addis Ababa University
BCG	Bacille-Calmette-Guerin (vaccine)
BSC	Bachelor Of Science
CHAI	Clinton Health Access Initiative
DPT-HepB-Hib	Diphtheria, Pertussis, Tetanus, Hepatitis B and Haemophilus Influenza B
ECSA	Ethiopian Central Statistics Agency
FMHACA	Food, Medicine, and Health care Administration and Control Authority
FEFO and FIFO	First Expiry-First Out and First In -First Out
EPSA	Ethiopian Pharmaceuticals Supply Agency
EVM	Effective Vaccine Management
EPI	Expanded Program on Immunization
ETB	Ethiopian Currency(Birr)
FMOH	Federal Ministry Of Health
HC	Health Center
IPV	Inactivated Polio Vaccine
NGO	Nongovernmental Organization
NMOH	Newzland Ministry Of Health
OPV	Oral Polio Vaccine
PCF	Population Correction Factors
PFSA	Pharmaceutical Fund and Supply Agency
PCV	Pneumococcal Conjugate Vaccine
Rota	Rotarex Virus
SPSS	Statistical Package for the Social Sciences
TT	Tetanus Toxoid
UNICEF	United Nations Children's Fund
VVM	Vaccine Vial Monitor
VVMP	Vaccine Vial Monitoring Police
VWR	Vaccine Wastage Rate
WHO	World Health Organization

Abstract

Assessment of vaccine wastage and contributing factors in selected health centers of Addis Ababa, Ethiopia.

Tesfahun Tawye, Addis Ababa University, 2019

Introduction: Vaccine is life saving biological product that produces and enhances immunity to the vaccine-preventable diseases for which it is targeted. Vaccination prevents an estimated of 2.5 million deaths globally each year by reducing morbidity and mortality of children. Vaccine is a temperature sensitive product that needs special handling not to be waste. Even though vaccine wastage cannot eliminate totally at least it can be reduced to the possible minimum level by ensuring effective vaccine management.

Objective: The objective of the study was to assess the wastage rate of vaccines and vaccine wastage contributing factors in health centers, Addis Ababa.

Method: Method of study was a descriptive cross-sectional study design. Sample size selected using a simple random sampling (lottery) method after allocation of the sample size proportionally into ten sub-cities based on number of health centers.

Result: The highest wastage rates of vaccine were 29% (Measles) which is lyophilized and 26% (TT) and both are liquid and multi-dose vial vaccines. The low wastage rates were 6.5 % and 7% for Rota and pentavalent vaccine, respectively. These are single-dose liquid vaccines. The total wastage rates of vaccines were 22 %(202,224 doses) out of which 15% accounted for open vial vaccine wastages and 7% of them were close vial vaccine wastage. The total vaccine wastage rate in terms of estimated cost was accounted for 8 % (103,512.25USD).

Conclusion and recommendation: The study showed high vaccine wastage rate for open, closed and lyophilized vaccines. The main reasons of open vial vaccine wastage were lack of ineffective application of in multi-dose vial policy in which, some liquid vaccines with multi – dose has to be discarded at the end of vaccination sessions. While the reasons of closed vial vaccine wastage were expiry due to ineffective stock management (over stock), improper application of first–expiry first-out and vaccine vial monitoring indicator change and freezing due cold chain management failure. The intervention to reduce vaccine wastage needs an effective implementation of stock management, cold chain management and multi-dose vial policy.

Keywords: vaccine, wastage, factors, open, close, vial, health, centers.

1 Introduction

1.1. Background

Immunization is the enhancement of body to resist an infection or toxin (immunity) after the administration of vaccines to prevent diseases. It is one of the most potential and economical of all public health interventions. It averts illness and disability and protects millions of lives from death every year. Vaccine used to reduce diseases incidence, prevalence, morbidity and mortality to local acceptable level (control), to reduce incidence of disease to zero level within defined geographical area (eliminate) and even for reduction of worldwide incidence infection caused by specific agent (eradication). Evidence demonstrates the use of immunization and it is one of the most successful and cost-effective health interventions. Vaccination prevents an estimated 2.5 million deaths globally each year (Bagdey *et al.*, 2017).

Immunization of children protects vaccine-preventable diseases to reduce childhood mortality, morbidity and disability across the world. Improving access to and utilization of routine immunization services are the best choice for the prevention and control of vaccine-preventable diseases (Meleko *et al.*, 2017).

Vaccination is the administration of relatively harmless agents that used to enhance immunity to protect vaccine preventable diseases and it is the most life-saving and cost-effective intervention for specific targeted diseases. Currently several new, but more expensive vaccines have become part of immunization programs in low and middle-income countries. Benefits of monitoring vaccine wastage are improving vaccine forecasting, uninterrupted supply of vaccines and minimize wastage. As the costs of vaccination increases countries become alert to better vaccine management considered as essential. Many low and middle-income countries, however, do not consistently monitor vaccine wastage (Usuf, *et al.*, 2018).

Vaccine is a temperature sensitive biological product that produces and enhances immunity to the particular Vaccine-preventable diseases for which it is targeted. Vaccine contains the disease-causing microorganism bacteria or virus, (or a portion) of it that is incapable of causing the actual disease (FMHACA, 2016).

In low- and middle-income countries, public sector immunization programs account for more fund and it has an economic burden on the country. Since vaccines are life-saving and temperature-sensitive products that need special handling, effective stock management, cold chain management, temperature monitoring and better immunization practice (WHO, 2005b).

Vaccination has been widely accepted and one of the most cost-effective public health interventions for disease prevention. Although high vaccination coverage has been registered, there are also a greater numbers of parallel, vaccine wastages worldwide, some of which could be reduced by better vaccine management practices and application of vaccine vial monitoring policy (WHO, 2015).

Once the vaccine potency has been lost by excessive heat or freezing, returning the vaccine to the normal storage temperature will not help the vaccine to regain its potency (WHO, 2015). Since vaccines are heat and freeze sensitive biological products, they may become less effective, or it can be destroyed when exposed to the high temperature outside the recommended range from $2C^{o}$ to $8C^{o}$ (Yakum, *et al.,* 2015). WHO considered the removal or discarding of remaining doses in lyophilized vaccine vials to be an unavoidable reason for vaccine wastage (WHO, 2017).

Monitoring of vaccine wastage helps to improve forecasting of required vaccines, ensure uninterrupted supply of vaccines and minimize vaccine wastage. Vaccine wastage is an essential and major factor for forecasting vaccine needs. In Ethiopia, there were 11 vaccines that are given to infants in a routine immunization program. These are Bacille-Calmette-Guerin (BCG), oral polio vaccines (OPV), Pneumococcal Conjugate Vaccine (PCV), Measles, Diphtheria-Pertussis-Hepatitis B, Haemophilus influenza type B (DPT-HepB-HiB), Rota, inactivated polio vaccines (IPV) and Tetanus anti-Toxoid(TT) for pregnant mothers (FMOH &PFSA, 2016).

Vaccine distribution is held through different multi-tier system of supply chain until it reaches the service delivery point ,where the client will receive the vaccines using refrigerator truck and cold box. During this process, the vaccines must be stored until the customer needs them. Inventory management is the process of maintaining of stock properly at all levels of the supply chain and at all time until the client used. The current practices of distribution of vaccines including Addis Ababa follows requisition and delivery of immunization supplies in every quarter from center to EPSA hub , and every month from EPSA hub to woredas and to sub-cities and then to service delivery point(FMOH and EPSA 2018).

Lacks of knowledge in effective vaccine management causes improper monitoring of vaccine wastage, and end up with inadequate forecast of needs and caused subsequent stock-outs or overstocks. Therefore determinations of vaccine wastage factors are crucial to all immunization points, the stores and monitor their use continuously. Such monitoring can provide the logistician with good guidance on the introduction of corrective actions to reduce

wastage whenever necessary. The incorrect Implementation of logistic related, policy-related and immunization practice-related factors are the main that cause vaccine wastage (WHO, 2005a). Routine vaccines cost represented approximately 20% of overall immunization program costs in low- and middle-income countries (WHO, 2017).

For the developing world, WHO estimates that adherence to the opened-vial policy has the potential to reduce wastage rates by about 30%, resulting in annual worldwide savings of US$ 40 million in vaccine costs (WHO, 2010). Several studies conducted in different countries showed a high percentage of vaccine wastage in different levels of health facilities (Wallace *et al*, 2017, Tiwari *et al*, 2017, Usuf *et al*, 2018). Based on the WHO recommendation the wastage rate of the vaccine in routine vaccination for different doses per vial indicated as follows

Table1.WHO recommended vaccine wastage for planning purpose (WHO, 2017).

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

According to Federal Ministry of Health (FMOH), the recommended vaccine wastage rates multi-dose vial vaccines were 50% for BCG, 25% for Measles, and 10% for others. The recommended vaccine wastage rate for single- dose vial vaccines like Pentavalent and Rota were 5% (FMOH and PFSA, 2016). Study of vaccine wastages was not done in the City administration of Addis Ababa. So, identification of the problem in and conducting of study on vaccine wastage is important for vaccine quantification and to recommend interventions for reducing vaccine wastage. The Addis Ababa City Administration health bureau (AACAHB) annual report showed that there was vaccine wastage due to expiry, VVM change due to other contributing factors. The report showed that vaccine wastage rate increment of some antigens and there were shortage of standardized refrigerator & spare parts (AACAHB, 2018)

The findings of this study might also help to be used as a baseline, deriving vaccine wastage for quantification and to identify vaccine wastage associated factors to recommend EPI program intervention in Addis Ababa city.

1.2. Statement of Problem

"*Vaccine wastage is defined as a loss by use, erosion or leakage through Expiry, VVM change (decay), damage by, heat exposure and freezing"*(WHO,2017). The two type's vaccine wastage are open vial wastage and closed vial wastage. Open vial wastage is wastage of discarded dose (remaining dose) after immunization session, client reaction requiring more than one dose, not being able to withdraw the numbers of doses during reconstitution, poor reconstitution practice, open vial submerged in water, contamination, and loss by use. Unopened vial wastage on other hand is wastage due to expiry, VVM changes, heat or freeze exposure, breakage, missing inventory (WHO, 2017). A study which was done in Gambia documented that vaccines exposed to high wastage rates were due to expiry, damaged by VVM and breakage respectively (Usuf, et al., 2018).

Study done in a tertiary health care centers of India showed high wastage rate of BCG (77.9%), TT (36.81%), 5 doses of Measles (41.28%) and Pentavalent (7.42%) (Gupta, *et al.*, 2015). Similar other study showed that vaccine wastage of BCG (66.84%), OPV (12.63%), and TT (22.57%) (Patle, *et al.*, 2017) and polio (15%) and Measles (50%) (Wallace, *et al*, 2017) which showed a higher wastage rate than the WHO recommendation (WHO, 2017). A study was done by the United Nation Children Fund (UNICEF) also showed higher wastage rate for liquid vaccines (38%) than lyophilized vaccines (50%) (UNICEF, 2010).

The study that was done in India indicated that wastage of vaccines in terms of cost was 3,087,880USD, 1,831,964USD, BCG 22,1417USD and 237,731USD for Measles, polio, BCG and TT respectively (Khonputsa, *et al.*, 2017). A study done in Africa like Cameron assured that there was total excess wastage of vaccine in terms of cost, like 605.11 USD for routine immunization which accounted 19.5 % vaccine wastage (Ebon and Levy, 2011).

Vaccine wastage can be expected in all programs but it could be reduced by ensuring effective vaccine management. Vaccine wastage usually caused by cold chain, temperature monitoring, storage, and stock management problems (WHO, 2005a).

Effective vaccine assessment done in nine regions of Ethiopia except AACAHB showed that wastage rate of BCG and measles vaccines were 60% and 25% respectively (FMOH, 2013). This has a negative consequence on accurate calculation of vaccines wastage. This leads to poor quantification/forecasting and causes either subsequent stock out or overstock and economical burden. Since the vaccine forecast is based on wastage factors, high vaccine wastage brought high artificial demand which increases unnecessary procurement and supply

chain or logistic cost. High vaccine wastage maximized demand for vaccines and which consequently increases unnecessary vaccine procurement and supply chain costs. Accordingly, efficient determination and usage of vaccine wastage or wastage factors for vaccine needs saved the partners and government funds for vaccination (Tiwari *et al*., 2017).

The WHO reports showed over 50% vaccine wastage around the world (WHO, 2005a). The WHO member countries would aspire for the highest wastage rate of 25% set for the first year with a plan to slowly reduce it to 15% by the third year and for "vaccine in single-dose or two-dose vials" the maximum wastage recommended is 5 %(WHO,2005a). In most of the WHO, member countries open vial vaccine wastage is much higher than closed vial vaccine wastage but the degree varies from country to country and facility to facility (Yang, et al., 2014). Vaccine wastage factor which derived from vaccine wastage of each vaccine is an important factor for quantifying and forecasting vaccine needs. In the non-existence at facility or national data on wastage rates, or if incorrect figures at facilities and national level are used, the country or the health facility may face serious vaccine shortages or be unable to consume received quantities, leading to increased wastage through expiry or damage by VVM (Patle et al.,2017). Studies in Africa (like Gambia, Cameroon) and India showed high vaccine wastage in routine immunization, especially BCG, polio and Measles vaccines (Usuf et al., 2018; Sharma et al, 2016; Ebon and Levy, 2011).

According to FMOH assessment of effective vaccine management (EVM) conducted by (FMOH,2013), there were gaps in vaccine stock management, multi-dose vial policy implementation, vaccine inventory system and vaccine storage temperature controlling which were contributory factors for vaccine wastage. There were also gaps in distribution, inventory (stock) management of vaccines, in reporting of vaccine wastage and in general the data quality of the report. There was no study or report of an open vial and closed vial vaccine wastage throughout the country and the facility reports were only the unopened vial vaccine wastage. Vaccine wastage increases mainly with poor implementation of policy, stock management, inventory control. Further, inappropriate procedures, distribution, poor cold chain management and freezes control contribute to vaccines wastage increases.

AACAHB annual report showed total closed vaccine wastage rate of BCG was 4.5% and Measles was 6 % .These vaccine wastage were due to expiry, VVM change, and other contributing factors. On the other hand interruption of some antigens occurred due to supply distribution problems, wastage rate increment of some antigens and shortage of standardized refrigerator & spare parts are also contributory factors for vaccine wastage. The City has

relatively better documentations to extract data for the research. Some challenges were poor distribution, shortage refrigerator (AACAHB, 2018).

1.3. Research Questions

The research questions of the study were:

- What are the wastage rates of each vaccine in routine immunization?
- What are the reasons for vaccine wastage in the routine immunization programs?
- What are the major contributing factors for vaccine wastage in routine immunization program?

1.4. Significance of the study

The aim of this study to identify vaccine wastage rate and vaccine wastage factors that are used to quantify vaccine and forecasting which is done based on the target population of infants and pregnant mothers. Determining the prevalence wastage rate vaccines put intervention and to reduce both closed and open vial vaccine wastage. The impact of such studies is tremendous in resource-limited countries like Ethiopia to helps to make informed decision for cost-effective health care system. The current study helps to capture modifiable reasons for vaccine wastage and contributing factors for vaccine wastage. So that, appropriate intervention can be conducted strengthen immunization coverage in the city in general. Moreover, the output of the study will further serve as a reference for auxiliary relevant studies.

1.5. Scope of the Study

The study was focused on wastage rate of vaccines and reasons of vaccine wastage in routine immunization and it was limited to in selected health centers of Addis Ababa city administration. This is because of resource limitation, availability of relative better vaccine stock management and good records.

2. Literature Review

The factors that cause vaccine wastages are policy-related (Multi-dose vial policy, VVM monitoring, Policy on storage), logistics-related factors (stock management, storage, and handling, transportation/distribution, vaccine-related factors (vial size/presentation), cold chain related factors (refrigerator, temperature control) immunization practice-related factors (poor reconstitution practice, vaccine discarded, contamination and vaccination coverage) (WHO, 2005a; WHO, 2005b).

2.1. Vaccine Policy and Training

The management of vaccine stocks is one of the main tasks in the EPI program. It consists of receiving, accepting, ensuring the required storing conditions and controlling the distribution of vaccines through the different structures (intermediary stores and immunization units). This is in order to ensure the quality vaccines for immunization programs (WHO, 2017). Government policies and procedures affect all elements of the Vaccine logistics system. Many countries have established policies on the selection and quantification of medicines. Without policy and procedures when items are distributed; where and how items are stored; and the quantities received by customers, it is difficult to manage vaccines and generally medicines (USAID | DELIVER PROJECT, 2011a). The study done in Mozambique showed that 59.6%) of health workers involving in EPI were ever attended training on storage, distribution and handling Procedures of vaccines in the cold chain (Carlos, *et al.,* 2007). Since vaccines are expensive and temperature-sensitive products, all the health workers working in the EPI clinics should be trained on the application policy on cold chain management and handling temperature monitoring, vaccine stock management, application and stock recording of vaccines, otherwise, the vaccine could be liable to wastage (WHO, 2017).

2.2. Vaccine stock management

All facilities must have written policies, procedures and protocols in place regarding vaccine management (WHO, 2015). The study was done in Gambia in 100% of health centers recorded beginning balance, ending balance, receipt, issued and used of a vaccine in ledger book but not on bin card and stock record card (Usuf, *et al*., 2018). The study conducted in Cameroon also showed 78.6% health centers had an inappropriate arrangement of vaccines in refrigerators (Yakum, *et al.,* 2015). The study done in India showed vaccine wastage by expiry was high and broken was less, and very few stores were recording wastage information and fewer are reviewing it to make use for improving the program (Panika, *et al.*,

2018). In the assessment done in of some regions of Ethiopia showed that there was a mismatch between vaccines and diluents at some woredas and service delivery levels (UNICF, 2018).

According to FMOH Ethiopia conducted on EVM assessment showed 53% health facilities were achieved the FMOH over all EVM cutoff point (FMOH, 2013). Similar assessment was done by the Clinton Health Access Initiative (CHAI) and showed 61% of health centers did not do physical inventory (CHAI, 2018) and the assessment was done in Ethiopia on effective vaccine management indicated that 26.6% of health centers did not do physical inventory (FMOH, 2013). A good stock recording system is a valuable instrument in the management of vaccines. It includes the recording of the stock keeping records, transaction records, and stock consumption, different components of stock arrival, receiving, issuing, consumed, expiry date, manufacturing date, VVM and temperature of vaccine and other related supplies (FMOH &PFSA, 2016).

2.3. Vaccine cold chain management

Cold chain management is transporting, distributing, issuing, receiving and storing vaccines in the potent state from the manufacturer to service delivery point using and monitoring different temperature devices. A cold chain is a function of different elements, like human, material, financial resources, Policy and standards that ensure the high quality of vaccines and immunization programs. The cold chain consists of different levels, which deal with vaccine orders and supplies, transportation, storage, and distribution from the manufacturer to the point of administration up to the target population (WHO, 2017).

Cold box and vaccine carriers are heat insulated and passive containers which used store when refrigerator failures happened and during transportation. Cold boxes and Vaccine carriers require a supply of ice packs and sufficient refrigeration capacity to maintain cold chain of vaccines (CHAI, 2017).

In developing countries, 35% of most cold chain equipment were not functional and about 44% of the facilities did not fill their temperature charts systematically twice a day as recommended. The study done in Ethiopia on cold chain management showed that there were 22.8% of functional refrigerators and 85.7% fridge-tag (Jemal *et al*., 2019)). A study was done in India however, showed that adequate storage capacity for vaccines was 92.8 %(Panika *et al.*, 2018). Besides, there was evidence 85.7% of health facilities had a back-up system (contingency plan) in case of power failure (Ringo *et al., 2017*).

The study done in Kenya and Uganda showed that the health facilities stored vaccines outside the recommendation temperature were 26.2%, and 7.9% respectively with one instance time observation (Emily, et al., 2013). Vaccine potency was highly sensitive to the cold chain status. Because, vaccine lost its potency when exposed to excessive heat, cold, or light and once, it loses its potency cannot be restored. Those who receive the vaccine with reduced potency may not be fully protected against vaccine-preventable disease (Woldemicheal *et al.,* 2018). The study which was conducted in Gurage zone, Ethiopia reported, both the availability of refrigerator and fridge tag were 22.8% and 85.7 % respectively (Jemal, et al., 2019). While, the study conducted in the North-West Region of Cameroon in which 95.1% of health centers had a functional refrigerator with a working thermometer (Yakum, *et al*., 2015).

The assessment done by Clinton Health Access Initiative project in Ethiopia 99% of the facilities had enough storage facilities (CHAI, 2017) and assessment done in Ethiopia showed 82% of health centers also had storage facilities and adequate capacity to store vaccine(FMOH,2013). The previous study done in India showed that adequate storage capacity for vaccines was 92.8 % (Panika, *et al.,* 2018). The study done was in Ethiopia like Gurage zone 25% of the health centers stored laboratory reagents and maternity medicines with vaccines during the data collection period. A study in Bale South East Ethiopia, vaccines 17.14% health centers were stored in temperature read out of range which was above 8°C (Woldemicheal, *et al.,* 2018). This was not in line with the WHO recommendation that the vaccines store with temperature 2-8°C (WHO, 2017). The study was done in India however showed that 100% of the health facilities have separate space (Panika, *et al.*, 2018).

The previous study also showed that all the health centers opened and closed refrigerator door maney times a day during immunization which resulted in the temperature reading were $+18C^0$ much above that is required for vaccine storage (Carlos, *et al.,* 2007). The health centers that achieved an overall score on conditions of refrigerators (health centers that performed as per WHO recommendation) were 75.5% which was nearly the same as the FMOH assessment (FMOH, 2013). All health facilities must ensure they have the right personnel in charge of vaccine management that follow the right procedures to maintain the cold chain, ensure the right vaccine storage unit is available, the right temperature monitoring tool is used and the vaccine is stored at the right temperature. Therefore it is imperative for health professionals to follow the procedures and policies set out by World Health

Organization in order to ensure effective management of the cold chain for vaccine safety (Rittle and Childre, 2008).

The cold chain system is storing, transporting and utilized vaccines in a potent state from the manufacturer, supplier and to the client being immunized. It consists of a sequence of storage and transport links, all considered to keep vaccines within an acceptable temperature range $2C^{o}$ to $8C^{o}$ until it reaches the users. A shortage of experienced and well trained human resources can easily endanger the success of any health program, including an immunization program. The variables that can cause poor coverage are inadequate financing, poor vaccine quality, poor vaccination practices, and weak health care systems (Yakum *et al.*, 2015).

The cold chain system is highly sensitive to any kind of mishandling and power interruption of cold chain equipment. It is considered to be at most risk, mainly in tropical countries where power supply is unpredictable and facilities for its maintenance are not well developed. Poor cold chain management was observed both during the transportation and storage of the vaccines. Vaccine wastage contributing factors causes to poor cold chain management which resulted delays during transportation, very long storage at the health unit, offensive use of refrigerators, power disturbance, equipment breakage, and shortage of trained personnel capable of managing the cold chain. Vaccine storage in the refrigerator was observed to be improper in 47 (73.4%) of the functioning 64 health centers. Overstock of refrigerator causes inadequate air circulation between vaccine boxes, vaccines. There was no statistically significant difference regarding Vaccine stock management, storage and cold chain management between urban and rural sites (Birhane and Demise, 2010).

Some of the problems identified from the assessment done on effective vaccine management 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. In addition, the report of FMOH revealed that 35% of equipment was not functional, and 14% of the functional equipment was sub-standard equipment (FMOH, 2013).

2.4. Vaccine vial monitoring and immunization practice

The CHAI assessment findings revealed that 19% of health facilities do not use VVM for vaccine management, while and the rest 91% of them use VVM for vaccine management (CHAI, 2017). Addis Ababa health Bureau's annual report (AACAHB, 2018) and the situational analysis assessment of immunization supply chain management strategy indicated that there were delayed deliveries and near VVM stage delivery to health centers (FMOH and

EPSA, 2018).The study done in Gambia showed that 47.4% of the health centers were fully labeled the reconstituted vaccines with the date and time after opening (Usuf, *et al.*, 2018). The study also showed lyophilized vaccines discarded within six hours after the opening. The study was conducted in Nigeria indicated that 84% of the health workers were discarded the lyophilized vaccines and 47% of health workers discarded liquid vaccines after opening(Wallace, *et al.*, 2017).

2.5. Vaccine wastage

Vaccine wastage is the result of loss by use, decay, erosion. Wastage of vaccines due to damage from freezing is an ongoing problem. Freeze- damage vaccine consists of two risks; one option of risks is a freeze-damaged vial detected and therefore must be discarded, and another option is a freeze damaged vial that will not be detected and therefore might be administered. Freeze-damaged vaccine can be detected using a shake test (Goldwood *et al., 2018*).

Vaccine wastage can be classified in to two as closed and opened vials wastage. Closed vial wastage occurred due to expiry, VVM indication, heat exposure, freezing, and breakage. Vaccine wastage in opened vials may occur as the dose remaining in opened vial at the end of session are discarded, the number of doses drawn from a vial is not always the same as that indicated on the label, reconstitution practices are poor, open vials are submerged in water and also wastage occurs when contamination is suspected and the vaccine is discarded(WHO, 2017) The study done in a tertiary care center of India showed high vaccine wastage were BCG (77.9%), TT (36.81%) and, pentavalent (7.42%) Measles (41.28%) (Gupta, *et al.*, 2015), and Similar study BCG (66.84%), OPV (12.63%), and TT (22.57%) (Patle, *et al.*, 2017) and polio (15%) and Measles (50%) (Wallace, *et al*, 2017). The studies done by UNICEF in the different state of India, told as there were higher wastage rate vaccine (UNICEF, 2010). The assessment done in Ethiopia, on effective vaccine management showed that 60% BCG vaccine wastage (FMOH, 2013). The previous study was done in India also was indicated that liquid vaccines (26.36%) and lyophilized vaccines was (63.76%) (Gupta, 2015) and a similar study from UNICEF (2010) also showed higher wastage rate liquid was (38%) than lyophilized (50%). The study was done in India also showed that the wastage rate of lyophilized vaccine (23.3%) was higher than the liquid vaccine (20.66%) (Sharma, *et al.*, 2016).

World Health Organization recommends that closed vaccine vial wastage rate shouldn't be greater than 1%, if, EVM applied (WHO, 2017). The wastage rates of open vial vaccines

higher than open vial vaccines. Study in African country like Gambia showed closed vial vaccines wastage accounted for 4.1% and open vial vaccine wastage 95.9% from total wastage rate (Usuf, *et al.*, 2018). The study done in India showed that vaccine wastage of BCG (70.9%), OPV (48.1%), TT (62.8%) and measles (39.9%) (Chinnakali, *et al., 2017*). Studies in African countries, such as Nigeria and Gambia also revealed that there was a high wastage rate of open vial vaccines than closed vial vaccines (Wallace, *et al*, 2017) and (Usuf, *et al.*, 2018).

The higher the number of doses in the vials the higher will be the wastages, if the number of beneficiary attending immunization session is less but as the multi-dose vial is more cost-effective interns of cost and balance needs to be maintained regarding wastage of vaccine and cost of immunization using multi-dose vial policy (Sharma, *et al.*, 2016). Studies done in different countries showed that presence of vaccine wastage on 20 doses BCG (77.9%), 10 doses OPV (28.97%) and 10 doses TT (36.81%)(Gupta, *et al.*, 2015), BCG (66.84%), OPV (12.63%) and TT (22.57%) (Patle, *et al., 2017*) and BCG (70.9%)., OPV (48.1%), TT (62.8%) and measles(39.9) (Chinnakali, *et al.,2017*). Studies were done in Bangladesh, India, Mozambique, and Uganda showed that reduction vaccines wastage by 56%, 53%,53% and by 44% when 20 dose vial IPV vaccines switch to ten dose vial respectively(Yang, *et al.*, 2014).

The single-dose vial vaccines, such as PCV, Rota, Pentavalent and new coming vaccine, like IPV were more expensive than other vaccines. The study done was in India showed that, vaccine wastage in terms of cost like vaccines Measle (3,087,880USD), and TT (237,731USD) (Khonputsa, et al., 2017). A study done in Africa like Cameron indicated that there was overall excess wastage of vaccines like 605. 11 USD for routine and 591. 05 USD for outreach in each health center. The study done in Cameron also showed that wastage rate of two doses pentavalent vaccines interns of cost was72.7% in fixed immunization. The total average wastage rate of the study done by showed that overall vaccine wastage rate was 19.5 % in terms of cost (Ebon and Levy, 2011).

A study was done in Africa, like Nigeria and Gambia, showed that health workers perceived as 34% expiry,31% damage by VVM change and 11% damage by broken were the major reason of closed vial vaccine wastage; whereas freezing (5%) was the minor cause of vaccine wastage(Wallace, et al., 2017) and expiry (55.7%), damage by VVM change (59.5%), breakage and freezing (15.2%%) were the major reason of closed vial vaccine wastage(Usuf, et al.,2018). A study done in India also showed that vaccine wastage rate (VWR) of the BCG

vaccine was 66.84% , followed by OPV VWR 33.18% that needs high funds for the procurement of vaccines (Patle *et al.,* 2017).

Although vaccine wastage is simply quantifiable and forecasting using the target population of health facilities, other issues are more difficult to put into monetary figures as compared to saved life with immunization. These difficulties include safety, increased immunization, and other programmatic issues. In some situations, such as a change from multi-dose vials to single-dose vials where wastage of an expensive vaccine is high, cost savings would be obvious, thus safety and programmatic benefits would be its additional benefits. In other situations, there could be more costs in switching multi-dose vial vaccines to single-dose vials vaccines that would have to be weighed against the value of increased injection safety in injectable vaccines or program enhancements (Drain *et al.*, 2009).

According to the New Zealand Ministry of Health (NMOH) Guidelines indicated that vaccine storage, distribution, freezing and subjecting vaccines to heat are the most common reasons for vaccine damage and ultimately to vaccine wastage(NMOH, 2012). According to WHO guidelines, Diphtheria, Tetanus, cellular pertussis, Hepatitis B, Haemophilus influenza type B, Inactivated polio, Meningococcal, Pneumococcal and Rotavirus are freeze-sensitive. The most heat-sensitive vaccines are Measles Mumps Rubella, Inactivated polio and Bacille Chalmette Guerin (BCG). From this, it is concluded that vaccines can be damaged through both heat and freeze. This emphasizes that the cold chain system the major factor within an immunization program for vaccine wastage that vaccines are maintained at the correct temperature (WHO, 2017).

Effective vaccine utilization is an integral component of vaccine commodity security and vaccine wastage is one of the major factors to be considered to vaccine forecasting. The study done by UNICEF suggested that there was poor documentation of vaccine wastage at all levels. Wastage rates vary from country to country and among different vaccines. The study also showed maximum vaccine wastage at service delivery level, 27% for DPT and 61% for BCG at the outreach session site than a fixed site of the facility. In some vaccines, there was low wastage rate poor documentation and less monitoring of vaccine wastage in the supply chain is one of the responsible factors for this very low value. Session size, vial size, formulation (liquid vs. lyophilized, oral vs. injectable) also influences vaccine wastage (UNICEF, 2010).

The situational analysis report of Ethiopia showed that there were failures in updating the stock records in a timely manner, Poor recording and monitoring of wastage information at all levels of the country which have a negative result in extracting good quality of data, forecasting, procuring, supply planning. The presence of failures in updating the stock records in a timely manner, Poor recording and monitoring of vaccines wastage were the great challenges in higher decision making officials (FMOH and EPSA, 2018). Vaccine wastages are due to poor cold chain and stock, management, poor quantification, nature of the vaccine, poor temperature monitoring, and improper maintenance and usage of cold chain equipment, interrupting the supply of power (electric, solar, kerosene) and poor immunization practice. These result in vaccine wastage of vaccines and have a negative impact on the supply of vaccines and generally immunization programs (FMOH&PFSA, 2016).

2.6. Conceptual framework

The conceptual framework was developed using the pharmaceutical stock management plan and monitoring guideline. The problem tree analysis model is used to create awareness of the problem by identifying the fundamental causes and their most important effects (PFSA, 2014). The problem tree analysis model developed after reviewing WHO guidelines (WHO, 2005a: WHO, 2005b).

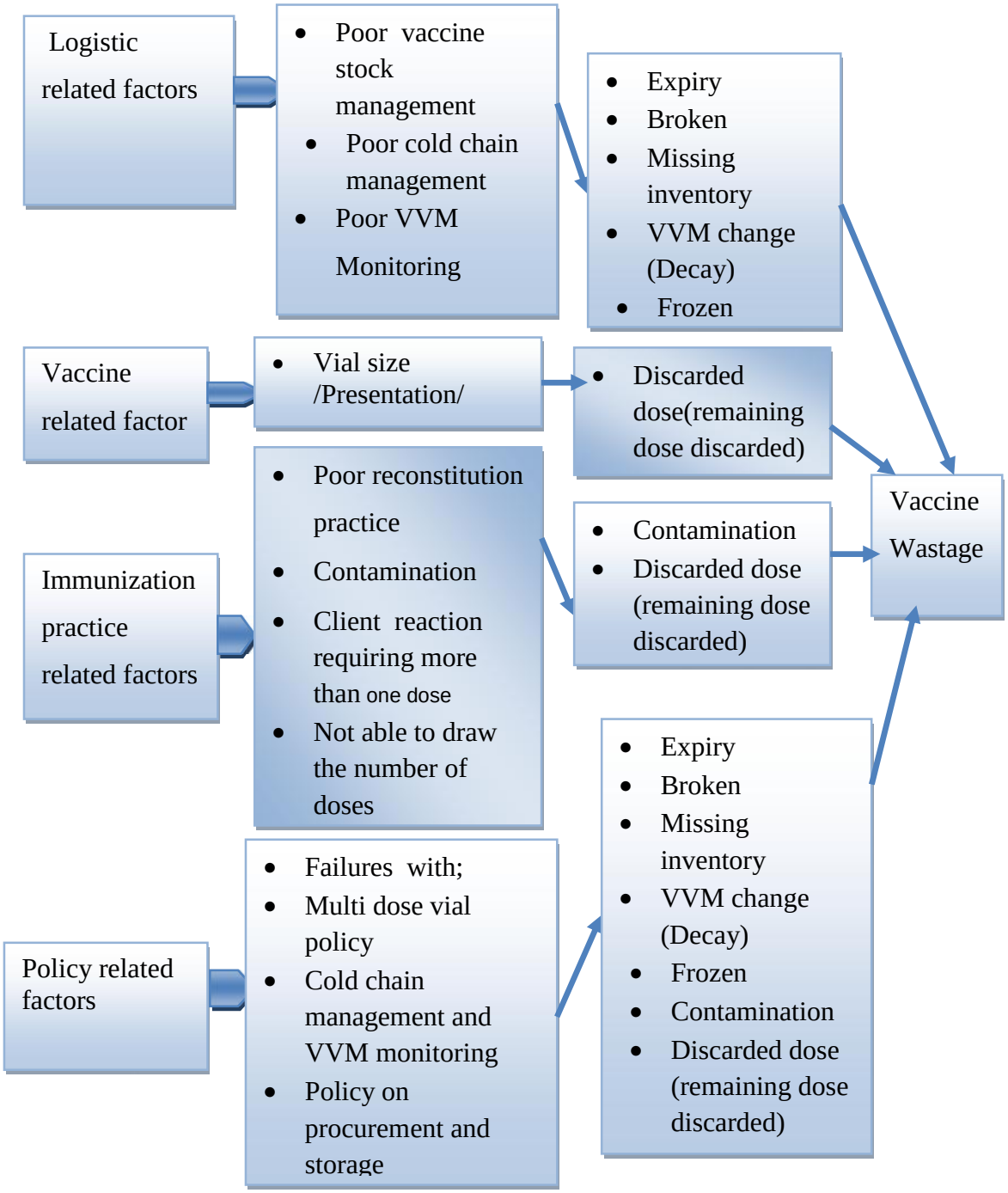

Figure 1. Conceptual framework adapted from vaccine management guidelines (WHO, 2005a; WHO, 2005b).

3. Objective

3.1. General Objectives

To assess vaccine wastage and contributing factors in health centers of Addis Ababa, Ethiopia.

3.2. Specific Objective

- To assess wastage rate of each EPI vaccine in health centers, Addis Ababa city Administration, Ethiopia.
- To assess the monetary value of vaccine wastage in health centers, Addis Ababa city Administration, Ethiopia.
- To assess contributing factors of vaccine wastage in health centers, Addis Ababa city Administration, Ethiopia.

4. Method

4.1. Description of Study Area

Addis Ababa is the capital city of Ethiopia. Its location is at the geographic center of the nation and covers about 540 Km^2. Administratively subdivided into 10 sub-cities and 116 Woredas. There were a total of 14 public hospitals, 106 health centers and 53 private and Nongovernmental organization (NGO) health facilities provide EPI services (AACAHB, 2017). Among the federal owned hospitals 4 are under the Federal Ministry of Health (FMOH), one under the Addis Ababa University, and the remaining 3 hospitals are owned army and police. Under Addis Ababa City Administration there are six general hospitals and 106 health centers. According to the Ethiopian central statistics report, population, of Addis Ababa was estimated 3.55 million with a growth rate of 3.8% (ECSA, 2018). Addis Ababa City Administration Health Bureau report showed that 78,751 under 1year (surviving infants) with annual growth rate of 2.24% and under 5 year 253,129 children with growth rate of 7.2%. The expected numbers of pregnancy mothers were 81,915 with growth rate of 2.33%. Even though, as a city and each sub-city, the overall administrative coverage of vaccination of children was 100%, there were 12% dropout rates and which did not mean that all children vaccinated and this indicated that under plan of the immunization service. This is due to the current population of Addis Ababa City Administration my not exactly the same as Ethiopian Central Statistics estimation taken for planning. The Sub-Cities which had a maximum dropout rate were Kirkose sub-city (25%) and Arada sub-city (17%). The Sub-cities which had minimum dropout rate were Lideta, sub-city (2%) and Nifasilik lafto sub-city (3%) (AACAHB, 2018).

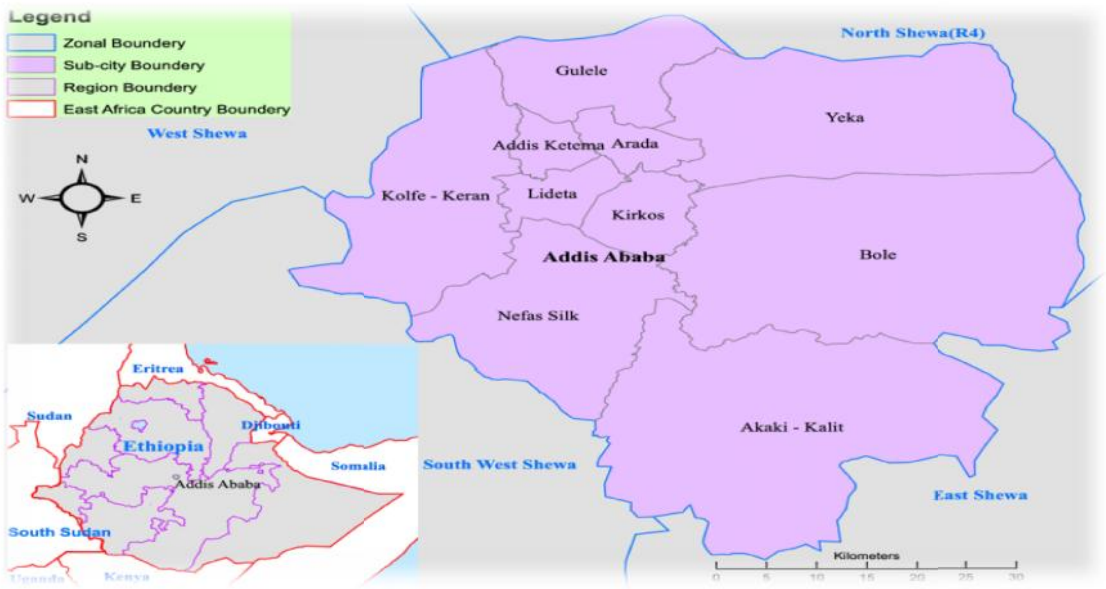

Figure 2. Map of Addis Ababa city Administration (AACAHB, 2018).

The regular flow of vaccines was from the Ethiopian pharmaceutical supply agency (EPSA) of Addis Ababa branch through sub-cities to health centers. The flow of vaccines logistic in formations from Ethiopian Pharmaceutical Supply Agency (EPSA) through sub-cities to health centers and from health centers to sub-cities, health Bureau, EPSA and FMOH.

The health centers requested vaccines needs for EPSA and FMOH using Vaccines Requisition Format (VRF) through Sub-Cities to regional health bureau. Some of the health centers of the EPI clinic assigned two health professionals one was the vaccinator and the other was a data recorder. The health centers had given immunization services for under one year children in a fixed site at facilities level. Health centers assigned two health professionals to the EPI clinic. One was a vaccinator who took EPI training (certified) or in-service training and the other was a data recorder (AACAHB, 2017). The facilities gave immunization services based on schedule once a week for measles and BCG vaccines and other vaccines administered daily. The study done on selected regional health centers that give vaccination to less than one year of children.

4.2. Study Design

The study was followed a quantitative descriptive cross-sectional study design to determine vaccine wastage and contributing factors for vaccine wastage among health centers in Addis Ababa, Ethiopia.

4.3. Source Population

The source populations of the study were all health facilities and all health professionals who were working in EPI program which were under Addis Ababa city administration.

4.4. Study Population

The study populations were health centers that give vaccination for all antigens of children under one year and TT for pregnant women. And also health professionals were working in the EPI clinic of Addis Ababa city administration.

4.5. Inclusion and Exclusion Criteria

Inclusion:

- ✓ All public health centers that provide routine immunization service of all vaccines for children and pregnant women.
- ✓ All public health centers had complete vaccine stock records throughout the year
- ✓ And health professionals who trained on EPI were included in the study for interview.

Exclusion:

- ✓ Health centers that did not have the last one-year vaccine stock record.
- ✓ And six Health Center that did not provide vaccination for all antigens were excluded.

4.6. Sample and Sample Size Determination

The sample size (n) required to conduct assessment was determined using USAID deliver project LIAT and LSAT guide to supply chain assessment for infinite and finite population with 90% confidence level (with t = critical value= 1.64), p = prevalence vaccine wastage of the population= 0.5 and 10% margin of error (m) and needs to be multiplied by the finite population Correction factor (USAID|DELIVER, 2011b).

$$n = \frac{t2*p\ (1-P)}{m2}$$

And using finite population correction factors (FPC):

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

Where:

New n = the adjusted sample size

N = the population size

n = the sample size found from the general formula

The total sample sizes were (n=42) Health Centers and 42 EPI focal person selected in each selected health facility who was directly involved or selected purposively for interview using structured questionnaires with the assumption of response rate of 100%.

4.7. Sampling Procedures

There were a total of 106 health centers in Addis Ababa City Administration, Out of which six new health centers were excluded from the Study Population due to absence of one year full vaccination service history and records. The sample size (42 Health Centers) were allocated proportionally to 10 sub-cities based on the number of health centers within sub-cities (Annex IV). The allocated Health Centers were selected with simple random sampling (lottery) method from the list of Health Centers obtained from the Addis Ababa Health Bureau was used to prepare sample frame (AACAHB, 2018).

4.8. Data Collection and Study Period

The data for vaccine wastages and vaccine wastage contributing factors were collected by two trained nurses who took training using structures questionnaires. The information for the study of vaccine wastage rate was extracted quantitatively by direct review of one-year

retrospective data of primary and reasons for vaccine wastage was extracted quantitatively by direct review of primary data sources. The data sources of for these data collection were Ledger book and Health Management Information System (HMIS) report.

The data collection for vaccine wastages contributing factors were collected by; document reviews, observation and interviews (demographic data and training only) using structured questionnaires (Annex II). The sources of data for contributing factors were ledger book, temperature monitoring chart, cold chain management report, temperature records and fridge tag. One year of retrospective of data given period May/ 2018 to April /2019 were collected. The data collection was done from May 1 to June 26 2019.

4.9. Data Collection Instrument

The vaccine wastage data collection tool and reasons of vaccine wastage (data extraction format) was adapted from WHO vaccine wastage at country level guideline (see Annex III) (WHO, 2005a).

The vaccine wastage contributing factors tool (which are factors related to policy, vaccine vial size, logistics, immunization practice, stock management, cold chain management, and vaccine storage temperature) were adapted from WHO monitoring vaccine wastage at country level guideline for program manager and World Health Organization vaccine management assessment tool of vaccine and biological products respectively (see Annex II) (WHO, 2005b; WHO, 2005a).

4.10. Data Quality Assurance

In order to assure the quality, the data was collected by trained data collectors. A half-day training was given to data collectors on how to use the data collection instrument, how to collect data, how to communicate the responsible personnel and ethical consideration during data collection. The study used WHO validated tool of effective vaccine management and monitoring vaccine wastage at the country level (WHO, 2005b; WHO, 2005a) and with the addition of expert opinion. The Pre-test was done in five health centers (which were not included in the study) to make data collector familiar to the data instrument, and to assure the feasibility of the data. The principal investigator was also trained and certified on EPI and had work experience of around three years and who investigated completeness and data quality of the data instrument. The principal investigator supervised the data collection process, completeness, and flow.

4.11. Data Analysis

The analysis of the study done with descriptive statistics data analysis for calculating vaccine wastage rate each vaccine terms of items and cost, closed vial wastage, open vial wastage, single and multi-dose vial wastage of vaccine were analyzed using excel spreadsheet based on the formula below (Wallace *et al*, 2017; Sharma *et al, 2016*; WHO, 2005a).

- Vaccine wastage rate=$\frac{\text{(beginning+received)doses}-\text{(ending +administered) doses}}{\text{beginning dose + received dose – ending balance dose}}$ x100
  (from issued stock)

- Vaccine wastage rate=$\frac{\text{(beginning+received)doses}-\text{(ending + administered)doses}}{\text{Beginning dose + received dose}}$ x100
  (from available stock)

- Closed vial vaccine wastage rate = $\frac{\text{Doses discarded (closed)x100}}{\text{Beginning dose + received dose - ending dose}}$
- Opened vial vaccine wastage rate = total wastage rate - closed wastage rate

Data analyses for the vaccine wastage contributing factors for wastage of vaccine were done by the descriptive data analysis of the statistical package for social science (SPSS), version 20 and imported to excel sheet.

4.12. Ethical Consideration

Ethical approval was obtained from the research and Ethical Review Committee of the School of Pharmacy, Addis Ababa University ERB/SOP/73/04/2019 (Annex VI) and ethical committee of Addis Ababa city administration Health Bureau ኦ/ኦ/ጤ/3667/227 (Annex VII). The study was conducted in each selected health centers after obtaining permission from the relevant bodies the respected health centers. The participants of the study were also asked for consent before participating in the study. During the consent process, they were provided with the information regarding the purpose of the study, why and how the sample selected to be involved in the study and what is expected of them and that they can withdraw from the study at any time. The data collector was assured about the confidentiality of the information obtained in the course of the study by not using personal opinion.

4.13. Operational Definition

Vaccine wastage: is a loss by use, decay, erosion or leakage due to expiry, vaccine VVM changes, heat or freeze exposure, breakage, loss by use and missing inventory (WHO, 2017).

Opened vial wastage: is wastage at the end of a session is discarded, the number of doses drawn from vial reconstitution practices is poor, doses remaining, submerged in water, and contaminated (WHO, 2017).

Closed (unopened vial wastage): Due to leakage, expiry, VVM change, heat exposure, freezing, breakage, missing inventory and theft (WHO, 2017).

Issue dose: The sum of administered (used) and wasted vaccine doses (USAID|DELIVER, 2011b).

Discarded dose: Doses discarded after immunization session, contamination, client reaction requiring more than one dose and not being able to draw the number (WHO, 2017).

Presentation of dose: Number of dose in a single vaccine vial (WHO, 2017).

Doses used: are doses administered (FMOH, 2016).

Pentavalent: DPT-HepB-Hib (FMOH, 2013)

Contributing factor: Factor that causes vaccine wastage (Pillay, 2014).

Transferred doses: Number of doses that move from certain facilities to other facilities, when facilities face a shortage of some vaccines (FMOH, 2013)

Available stock: is total number of stock available within certain period of time (USAID|DELIVER, 2011b).

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5. Result

The study findings include vaccine wastage rate of each vaccine and the overall wastage rate of vaccine in terms of dose and cost, wastage rate of open and closed vial vaccine, single-dose vial and multi-dose vial vaccine wastage, reasons and contributing factors of vaccine wastage. Out of the 42 health centers 70% covered by the study between 100% to 140% coverage for pentavalent vaccination and 30% had between 65%-99% fully vaccination coverage performance of their annual coverage (Annex V).

5.1. Vaccine wastage Rate

The number of antigens that were given to children and pregnant mothers were eleven and out of which TT was given to pregnant mothers. Majority of the doses given to the children were 145,513 (polio) followed by 108,939(PCV). Small numbers of doses given to the children were 40,288(IPV) and 50,496(Measles). High wastage rate of vaccines in the study period were 49.3 % (BCG), 29% (Measles), 26.5 % (TT). The wastage factors were 1.97 for BCG, 1.4 for Measles and 1.3 for TT. The low wastage rate of vaccines in the study period was 6.5 % (Rota) and 7 %(pentavalent) with wastage factor 1.2 and 1.3 respectively. Therefore, this was the major finding of this study.

Table2.Vaccine wastage rate and wastage factors for different vaccines in sampled health centers, Addis Ababa, Ethiopia, 2019(n=42).

types of vaccine	Total doses available	Doses issued	Doses used	Doses wasted	wastage rate	Wastage factors
Measles*	108,397	71,128	50,496	20,632	29%	1.4
BCG*	173,278	143,176	72,590	70,585	49.3%	1.97
Polio#	180,941	166,622	145,513	21,109	12.67%	1.14
Pentavalent#	132,407	112,020	104,120	7,900	7%	1.07
PCV#	148,787	126,107	108,939	17,168	13.6%	1.15
Rota#	102,659	86,861	81,182	5,679	6.5%	1.06
IPV#	731,199	64,311	40,288	14,023	21.8%	1.2
TT#	137,929	115,420	69,194	30,669	26.5%	1.3

*Lyophilized vaccine; #Liquid vaccines.

The average wastage rates of the lyophilized vaccines were accounted 39.15% which were higher than average liquid vaccines wastage rate (14.4 %).

5.2. Open and closed vials vaccines wastage rate

As indicated in Table3, pen vial vaccines wastage rate of Polio, Measles, BCG, PCV, IPV, and TT were higher than closed vial vaccines wastage rate. But, the open vial vaccine wastage rate of Pentavalent and Rota was lower than the closed vial vaccine wastage rate. Among open vial vaccine wastage rate, BCG (42.8%) accounted for more wastage rate and Rota (1.3%) was accounted for lower open vial vaccine wastage rate. Among closed vial vaccine wastage rate, Measles (12.5%) accounted for more wastage rate and Pentavalent (4.9%) was accounted for lower open vial vaccine wastage rate. Since pentavalent and Rota vaccines were single dose vaccines, open vial vaccine of these vaccines smaller than closed vial vaccines with poor effective vaccine management.

Table3.Wastage rate of open and closed vials vaccines from available stock in sampled health centers, Addis Ababa, Ethiopia, 2019(n=42).

Types of wastage	Polio	Measles	BCG	Penta Valnt	PCV	Rota	IPV	TT
Open vial wastage	6.87%	16.5%	42.80%	2.1%	8.6%	1.3%	16.1%	15.5%
Closed vial wastage	5.8%	12.5%	6.50%	4.9%	5%	5.2%	5.7%	11%

5.3. Reasons for vaccine wastage

As shown in Table 4, the major reason for vaccine wastage rate of measles and TT was expiry. The major reason for vaccine wastage of BCG and Oral Polio vaccines was VVM change and the major reasons for Rota and IPV was freezing.

Table4. Reasons for vaccine wastage from available stocks in sampled health centers, Addis Ababa, Ethiopia, 2019(n=42).

Factors	Polio	Measles	BCG	Pentavalent	PCV	Rota	IPV	TT
Expiry	1.4%	9.48%	1.5%	2.6%	2.5%	1%	1.2%	8%
VVM change	4.40%	3%	3.2%	0.75%	0.15%	0.7%	0.3%	0%
Freezing	0%	0%	0.4%	1.4%	2%	3.4%	4%	2.4%
Broken/contamination	0.01%	0.02%	0.15%	0.15%	0.32%	0.1%	0.14%	0.35%
(Inventory missing)	--	--	1.25%	--	0.03%	--	0.06%	0.25%

5.4. The overall (total) wastage rates of open and closed vial vaccines.

The average total wastage rate of closed vial vaccines was 7% which was higher than open vial vaccines was 15%.

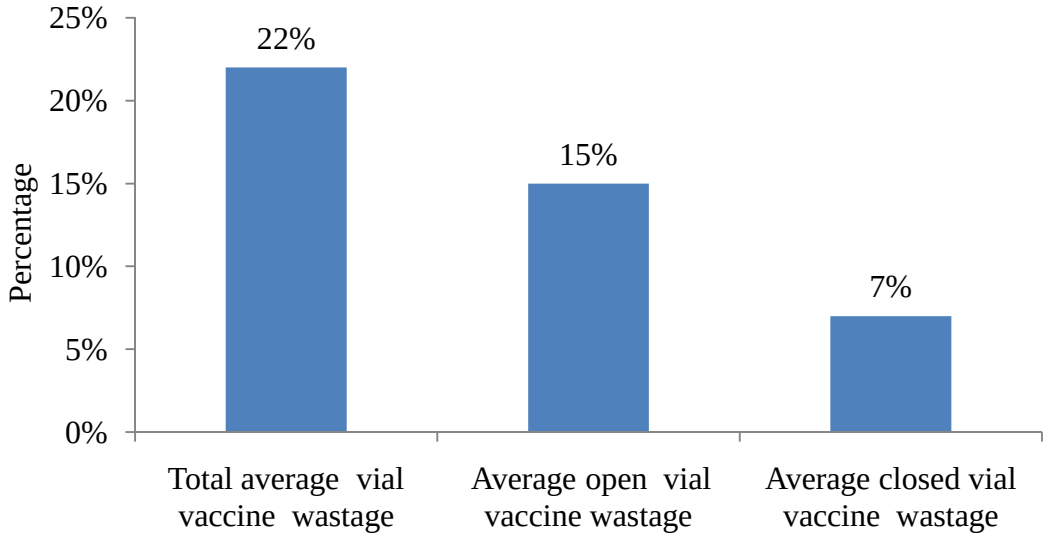


Figure 3.Average wastage rate of open and closed vials vaccines in sampled health centers, Addis Ababa, Ethiopia, 2019(n=42).

5.5. Wastage rate of different single and multi-dose vial vaccines

As shown in Table 5, single-dose and multi-dose vial vaccines were included in the Ethiopian national immunization program. Multi-dose vial antigens found to be accounted for more vaccine wastage than single-dose vial vaccines; which resulting 49.3 % (BCG), 29 %(measles) and 26.5 % (TT). However, vaccine with single-dose vial presentations like, Rota and Pentavalent vaccines were low vaccine wastage, which resulted in 6.5% and 7% respectively.

Table5.Vaccine wastage rate for different single and multi-dose vial vaccines in sampled health centers, Addis Ababa, Ethiopia, 2019(n=42).

S.no	types of vaccine	Presentation of dose per vial	Scheduled dose	wastage rate
1	Polio	10	4	12.67%
2	Measles	10	1	29%
3	BCG	20	1	49.3%
4	IPV	10	1	21.8%
5	TT	10	4	26.5%

6	Pentavalent	1	3	7%
7	PCV	2	3	13.6%
8	Rota	1	2	6.5%

5.6. Vaccine wastage by monetary value

In terms of monetary value, the two top vaccines wastages of vaccines were during the study period were recorded for PCV (49,670.81USD) and Rota (10,408.93USD). The most expensive vaccines per dose were single-dose vial vaccines (PCV, Rota and pentavalent). These accounted for higher monetary value with low vaccine wastage. The average unit cost per dose of PCV and Rota 2.893USD and 1.832USD which were higher than other antigens respectively (Table 6). Conversion to monitory value calculated using UNICEF vaccine and injection safety price list available for GAVI (Cost available to low income and GAVI supported countries (UNICEF, 2017).

Table 6.Wastage of vaccines in average monetary value (Average cost) from available stock (doses) in Ethiopian Currency (ETB) and USD in sampled health centers, Addis Ababa, Ethiopia, 2019(n=42).

Types of vaccine	Available cost(USD)	Issued cost(USD)	Used Cost(USD)	Wastage Cost (USD)	Unit cost /Dose(USD)
Polio	29,134.57	26,82.9	23,430.06	3,398.92	0.161
Measles	28,587.41	18,758.5	13,317.25	5,441.254	0.263
BCG	340,68.2	28,149.86	14,271.93	13,877.72	0.196
Pentavalent	136,985.2	115,893.2	107,720.1	8,173.153	1.034
PCV	430,473.6	364,855.3	315,184.5	49,670.81	2.893
Rota	188,161.8	159,205.9	148,797	10,408.93	1.832
IPV	525,471.8	46,216.71	28,952.73	10,077.55	0.718
TT	110,81.07	11,08.12	55,58.976	2,463.916	0.080
Total	1,383,964	736,870.5	657,232.5	103,512.25	----------

The two most wastage rates of vaccine by monetary value were 40.7 %(BCG) and 22.2% (TT), which were accounted for by more vaccine vial wastage than others, but when considered with the same doses of vaccines, PCV and Rota had higher wastage than other vaccines. The three lowest wastage rates of vaccine by monetary value were 1.9 % (IPV), and 5.53 % (Rota) respectively (Figure 4).

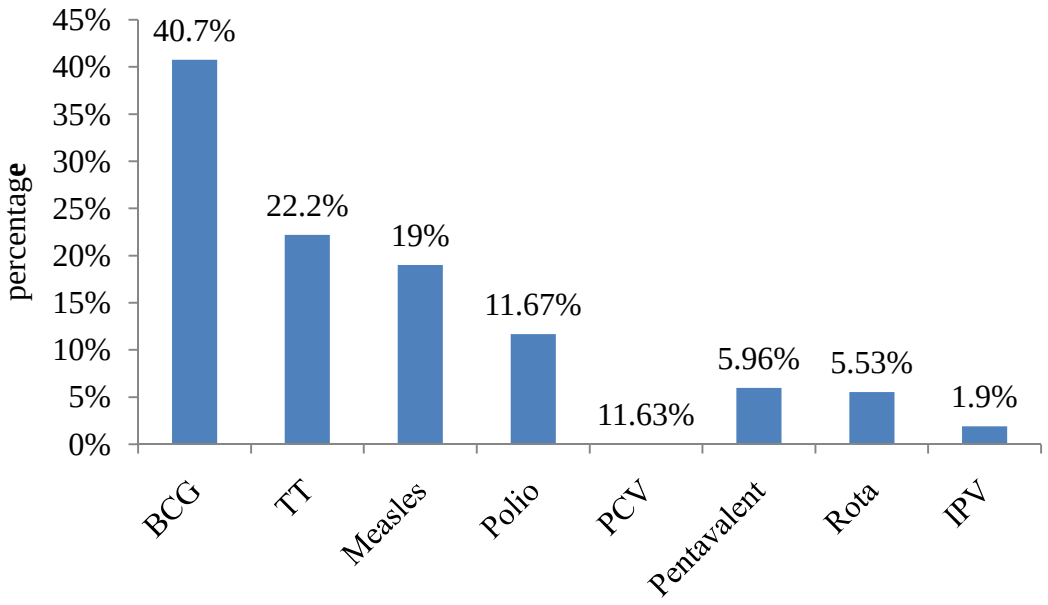


Figure4. Wastage rate of vaccine by monetary value(cost) from available stock cost in sampled health centers, Addis Ababa, Ethiopia, 2019(n=42).

5.7. Overall (average total) wastage rate of vaccine by monetary value (cost)

The study showed that the overall (average total) vaccine wastage rate of all vaccines by cost was 8% and 14.3% from available and issued cost respectively (Figure 5).

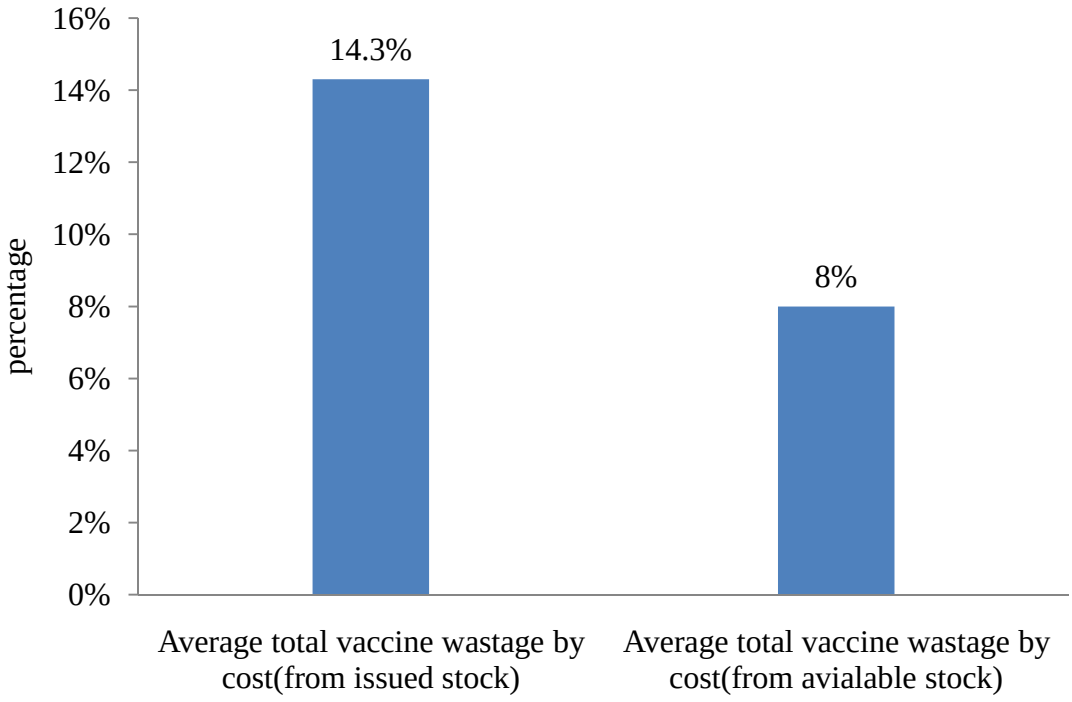


Figure 5.Overall (average) total wastage rate of vaccine by cost in sampled health centers, Addis Ababa, Ethiopia, 2019(n=42).

5.8. Vaccine wastage contributing factors

5.8.1. Socio-demographic characteristics

From a total of 42 EPI focal persons who provided information were females (86%) and 47% of EPI focal persons were nurses.

Table7. Socio-demographic characteristics of Health professionals (EPI focal persons) working in the selected health centers, Addis Ababa, Ethiopia, 2019 (n=42).

socio-demographic profile		No	%
Sex	Male	6	14
	Female	36	86
Age	20-30 years	24	59
	31-40 years	13	31
	>41 years	5	12
profession	Diploma nurse	20	47
	BSC nurse	18	43
	Health officer	4	10
			59
work experience in EPI clinic	1-5 years	25	
	6-10 years	12	29
	>10 years	5	12

5.8.2. Training

The findings revealed that most of the trainings for EPI workers given on immunization practice and cold chain management but quite low on vaccine stock management of vaccines (Table 8)

Table8. Immunization program training of staff in sampled health centers, Addis Ababa, Ethiopia ,2019 (n=42).

. Indicator	Frequency(yes)	
	No	%
Cold chain management.	39	92.8
Immunization practice.	39	92.8
Vaccine stock management.	22	52.3

5.8.3. Condition of refrigerator

As shown on table 9, the 13(31%) refrigerator's types were not appropriate as WHO Product quality list or standard. Thirty-five (83.3%) of the health centers opened the refrigerator's door more than two times a day during immunization sessions. There was evidence of 36 (85.7%) of health facilities conducted preventive maintenance (PPM) and curative maintenance to the available cold chain equipment.

Table9. Condition of the refrigerator in sampled health centers, Addis Ababa, Ethiopia, 2019, (n=42).

S.no.	Indicator	Frequency(yes)	
		No	%
1	The refrigerator type is appropriate for vaccines (Refrigerator with WHO, and UNICFE standard)	29	69
2	The refrigerator had adequate capacity to store adequate vaccines.	38	90.5
3	Vaccines are not stored near or on the door	22	52.4
4	Food or cool drinks are not stored in the same refrigerator that is used to store vaccines.	40	95.2
5	The refrigerator is lockable.	29	69
6	Refrigerator door opening during immunization sessions is minimized (two times a day).	7	16.7
7	The Health facility has a power back-up system in case of power failure (contingency plan).	35	83.3
8	Dedicated or separated room for vaccine Storage and immunization?	39	92. 9
9	The refrigerator is correctly packed with air circulating between the vaccines.	40	95.2
10	Evidence of preventive maintenance (PPM) and curative maintenance to cold chain equipment.	36	85.7
11	Availability of functional fridge-tag of the refrigerator.	42	100

5.8.4. Policy Application

As shown n in table 10, eight criterions were used in the availability and applicability of Policy, procedure and guidelines in health centers. There was evidence of the 34(81%) of health centers, adopted and applied written multi-dose vial policy (MDVP). Whereas, there

was evidence of the 36(85.7%) of health facilities had written instruction for preventive maintenance (PPM) and curative maintenance to cold chain equipment available. The study showed that 7(16.7%) and 8(19%) of there was no evidence of written procedures used for the shake test for frozen and Vaccine (IPV, PCV or TT) and written instructions on the use of vaccine vial monitoring (VVMs) respectively. There 10(25.8%) of the health centers opened vials of liquid vaccines were not kept for the next immunization sessions within 28 days.

Table 10.The policy application in sampled health centers, Addis Ababa, Ethiopia, 2019 (n=42).

S.no	Indicator	Frequency(Yes)	
		No	%
1	Policies available for vaccine stock management.	37	88.1
2	Evidence at the health facility that has adopted and applied MDVP.	34	81
3	Evidence of written instruction for preventive maintenance (PPM) of cold chain equipment available.	36	85.7
4	Written procedures used for shake test for frozen Vaccine (IPV, PCV or TT).	35	83.3
5	Written instructions on the use of vaccine vial monitoring (VVMs).	34	81
6	Opened vials of freeze-dried vaccines discarded within six hours of reconstitution, at the end of each immunization session.	31	73.8
7	Opened vials of liquid vaccines kept for the next immunization sessions within 28 days.	34	81
8	Evidence of written instruction for curative maintenance cold chain equipment.	21	50

5.8.5. Stock management of vaccines

As shown in table 11, there were 19 criteria for ensuring good vaccine stock management. A total of 42(100%) health centers had ledger books and had evidence of records of the beginning balance, ending balance, receipt, issued and used of the vaccine in the ledger book. But 36(85.7%) health centers had no bin card and stock record cards. The study showed that there was no evidence of 20(47.6%) vaccine wastage reports and 35(83.7%) wastage monitoring system whether it above the standard or not. The evidence showed that 8(19.1%) and 22(52.4%) health centers did not issued or administered using “first-expiry first-out” (FEFO) and firs in first out (vaccines had a similar expiry date) principle respectively. The

study showed that in 23(54.8%) of the health centers the vaccinators were given the priority to VVM change than expiry during immunization.

Table11. Stock management of vaccines in sampled health centers, Addis Ababa, Ethiopia, 2019 (n=42).

S.no	Indicator	Frequency(Yes)	
		No	%
1	Stock cards/ledger book for vaccines are kept.	42	100
2	EPI rooms have stock/bin cards.	6	14.3
3	Stock /bin cards for vaccines are correctly filled in.	4	9.5
4	Evidence of recording of beginning balance, ending balance, receipt, issued and used of the vaccine in the ledger book.	42	100
5	Discarded, dose presentation of vaccine and diluents and children vaccinated recorded in a ledger book.	40	95.2
6	Evidence of vaccines expiry date recorded.	40	95.2
7	Evidence of physical inventories of vaccine stock.	23	54.7
8	Evidence of the maximum stock level.	34	81
9	Overstock vaccines (Measles, Pentavalent, BCG, TT and IPV).	32	36.2
10	Vaccine wastage reports availability.	22	52.4
11	Vaccine wastage monitoring system.	7	16.7
12	The first in first out principle applies when issuing and using vaccines.	20	47.6
13	The vaccines were administered made according to the “first-expiry first-out” (FEFO) principle only.	34	80.9
14	Liquid/open and unused vaccines returned at the end of vaccination session (TT, polio, and IPV).	32	76.2
15	Vaccinator give the priority to VVM change than expiry during immunization	19	45.2
16	Sufficient syringes, needles and sharps containers were available for immunization session.	35	83.3
17	Vaccine stock corresponds with the diluents stock.	30	71.4
18	Evidence of expired vaccines in the facility stored separately from usable stock.	35	83.3

5.8.6. Storage and Cold chain management

As indicated in table 12, 34(81%) temperature refrigerators were not between 2 – 8ºC throughout the year and also 16(38.1%) of the health centers, did not documented all deviations outside 2 – 8ºC. The study indicated that14 (33.3%) facilities there did not completed records at least twice daily and for seven days per week manually.

Table12. Storage and Cold chain management in sampled health centers, Addis Ababa, Ethiopia, 2019 (n=42).

S.no	Indicator	Frequency(Yes)	
		No	(%)
1	Evidence of temperature recording sheet for vaccine refrigerators.	40	85.7
2	Evidence that the refrigerator has a fridge tag and it is being functional.	42	100
3	A working temperature motoring device (RTMD, fridge tag) placed in the center of the refrigerator.	32	76.2
4	Evidence of vaccine stock management based on temperature sensitivity.	25	59.5
5	A complete record at least twice daily and for 7 days per week manually.	14	33.3
6	The refrigerator has no alarm which is activated when the temperature exceeds8 degrees Celsius (8ºC) and falls below 2 degrees Celsius (2ºC).	28	66.7
7	Refrigerator temperature range not between (2 – 8ºC) throughout the year.	34	81.9
8	The responses to all deviations outside (2 – 8ºC) have been not documented.	16	38.1
9	Cold boxes/vaccine carriers available and in good condition.	25	59.5
10	Ice packs conditioned before use.	42	100
11	Temperature reading record (hard copy) sheet similar to the temperature reading on the fridge tag (check all alarms and reading)	36	85.7
12	Evidence of the presence of a refrigerator thermometer.	42	400
13	Number of facilities that had shake test for frozen vaccines.	11	26.2

5.8.7. Vaccine vial monitoring (VVM) and immunization practice

As shown in table 13, vaccines with VVM second were near to damage were delivered to 26(61.9%) health centers, and the 11(26.2%) health centers did not issued or administered according to the VVM status. The study showed that 11(26.2) health centers encountered vaccine-damage due to VVM change. In 20(52.4%) health centers reconstituted vaccines did not fully labeled with the date and time.

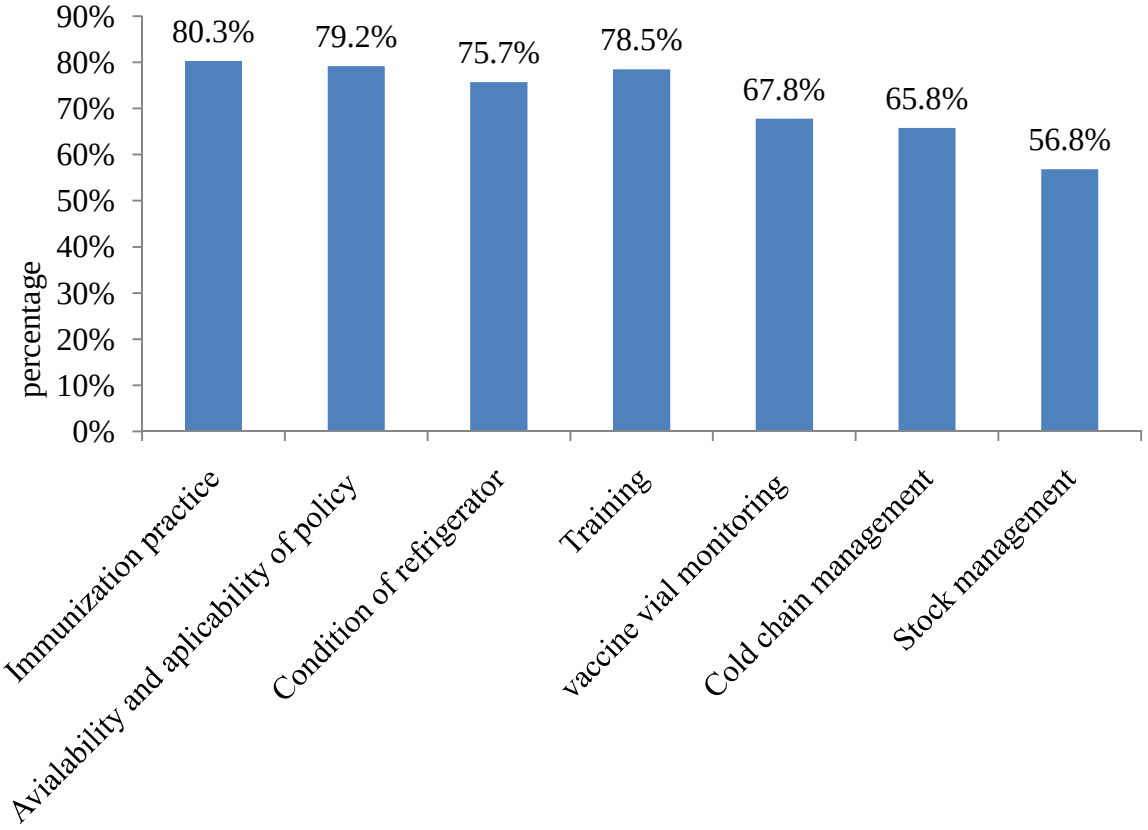
Table13. vaccine vial monitoring(VVM) and immunization practice in sampled health centers, Addis Ababa, Ethiopia, 2019 (n=42).

S.no.	Indicator	Frequency(Yes)	
		No	%
1	The vaccine administeration generally made according to the VVM status. See the administered and other vaccines.	31	73.8
2	The vaccine was not delivering with the second VVM stage.	16	38.1
3	Evidence of Vaccine VVM stages recorded.	42	100
4	Vaccines are used when the VVM stage is one and two.	42	100
5	Number of facilities that had damaged vaccines due to VVM change.	31	73.8
6	Reconstituted vaccines are fully labeled with the date and time.	32	76.2
7	Health centers have practices of client reaction requiring more than one dose	15	35.7
8	Not being able to draw the number of dose	11	23.8
9	The discarded doses of BCG and Measles after the opening of vaccines after 6hrs.	31	73.8
10	Number of vaccines contaminated.	10	23.8
11	Discarded doses of liquid vaccines after the opening of vaccines after 28 days.	34	81
12	Health centers did not administer lyophilized vaccines without a fixed schedule.	16	38.1

5.8.8. Average scores of contributing factors

As indicated in figure 6, Majority of the health centers did not meet WHO standards. Based on the findings, the health centers had slow performance of contributing factors according to

WHO standards for which in stock management, cold chain management and vaccine vial monitoring accounted (56.8%), (65.8%), and 67.8% respectively.



.Figure6.Average scores of contributing factors in sampled health centers, Addis Ababa, Ethiopia, 2019 (n=42).

6. Discussion

The study mainly focused on assessing vaccine wastage rate of lyophilized vaccine, liquid vaccines, and open, closed vial vaccines and its contributing factors. This study revealed that vaccine wastage rate was much higher in lyophilized (freeze-dried vaccines), open vial vaccines (both liquid and lyophilized vaccines) and multi-dose vial vaccines.

Regarding vaccine wastage rate, the study showed that high vaccine wastages of BCG, Measles, and TT with wastage rates 49.3 %, 29%, and 26.5 % respectively(Table 2), which is higher than WHO recommendation with wastage rate of Measles (20%), TT (20%)(WHO, 2017). This is also found to be higher than recommendation of Ethiopian Ministry of Health with wastage rate of Measles (25%), TT (10%), and the wastage rate of BCG was nearly the same as WHO and FMOH recommendation. Nevertheless, it was lower than the previous studies conducted in a tertiary care center of district of India with similar dose BCG (77.9%), TT (36.81%) and Measles (41.28%) (Gupta, *et al.*, 2015), and similar study BCG (66.84%), and TT (22.57%) (Patle, *et al.*, 2017). From this result it can be implied that there was better effective vaccine management; better stock management, cold chain management, vaccine vial monitoring and application of MDVP than the previous study but not as to WHO recommendation. The current study found that multi-dose vial vaccines had more wastage rate than single-dose vial vaccine. Since vaccine wastage was related to a number of doses in the vial. The higher the number of doses in the vials the higher would be the wastages.

Concerning multi-dose and single-dose vial vaccines, in Ethiopia vaccine like BCG and Measles were multi-dose vial vaccines, and are accounted for high vaccine wastage rate. This vaccines discarded after six hours of opening and for some liquids vaccines (TT, OPV, and IPV) which were multi-dose vial vaccines accounted for more vaccine wastage (Table 5). However, multi-dose vial presentation was more cost-effective in terms of cost (Table 6) but it exposed to more wastage. So, balance needs to be maintained regarding wastage of vaccine and cost of vaccines. Otherwise, wastage of liquid vaccines could be reduced by strong application of multi-dose vial policy (Sharma, *et al.*, 2016). Even though, vaccine wastage was expected, it could have been reduced to the possible lower wastage level as to WHO's recommendation.

Regarding open and closed vial vaccines, the current study indicated that open vial vaccine wastages were higher than closed vial vaccines wastage except Pentavalent and Rota. Closed vial vaccine wastage rate of Pentavalent and Rota higher than open vial vaccine wastage rate which was not in line of WHO's recommendation and this indicates that the health centers

had ineffective vaccine management. High open vial vaccine wastage was accounted for BCG (42.8%), Measles (16.5%) and TT (16.1%). The high close vial vaccine wastage was accounted for Measles (12.5%), TT (11%) and oral polio (5.8%) (Table, 3), which h was not in line of WHO recommendation (WHO, 2017). Studies in African countries, such as Nigeria and Gambia also revealed that there was a high wastage rate of open vial vaccines than closed vial vaccines (Wallace, *et al*, 2017) and (Usuf, *et al.*, 2018). The main cause of open vial vaccine wastage were poor application of multi-dose vial policy and the nature of lyophilized vaccines which can only be used for vaccination six hours after opening.

Regarding reasons of vaccine wastage, the major reasons of closed vaccine wastages were expiry VVM change, freezing, damage by broken and contamination (Table 4). The main causes of closed vial vaccine wastages were expiry, VVM change, inventory missing, freezing, damage by breakage and contamination (WHO, 2017). In some health centers Measles and TT expired because of overstock of vaccines and which had not redistributed to other health facilities which not had enough vaccine stock. A study was done in the Gambia documented that vaccines exposed to high wastage rates were expiry, damaged by VVM and damaged by breakage respectively(Usuf, *et al*.,2018). A study was done in Africa, like Nigeria and Gambia, showed that the health workers perceived as expiry (34%), damage by VVM change (31%), and damage by broken (11%) were the major reason of closed vial vaccine wastage; whereas freezing (5%) was the minor cause of vaccine wastage(Wallace, *et al.,* 2017) expiry (55.7%), damage by VVM change (59.5%), breakage and freezing (15.2%%) were the major reason of closed vial vaccine wastage(Usuf, *et al.,*2018). Vaccine wastage by expiry implied that there was over stock of vaccine and not using first-expiry first-out principles; as well as, vaccine wastage could be not prioritizing VVM than expiry. This implied that there were poor stock managements in some of the health centers. The overall current study wastage rates of the closed vial and open vial vaccines were 7% and 14.2% respectively. However, with the application of effective vaccine management, the wastage rate of close vial vaccines should not be greater than 1% for each vaccine (WHO, 2017).

Concerning lyophilized and liquid vaccines, the wastage rate of lyophilized vaccines was 42.5% (BCG) and 14.4% (Measles) because lyophilized vaccines discarded six hours after opening than liquid vaccines due to nature of vaccine and not follow the application of MDVP for 28 days. The result of the previous study also indicated the same pattern for liquid vaccines (26.36%) and lyophilized vaccines (63.76%) (Gupta, 2015). A similar study from

UNICEF (2010) also showed higher wastage rate liquid (38%) than lyophilized (50%). The study which was done in India also showed that the wastage rate of lyophilized vaccine(23.3%) was higher than the liquid vaccine(20.66%) and both lyophilized and liquid vaccines wastage rates were lower than the current study(Sharma, *et al.,* 2016). Due to high wastage rates of lyophilized vaccines, the health centers suffer from vaccine wastage and this may result in negative outcomes on vaccination coverage (WHO, 2005a). These implied lyophilized vaccines were heat-sensitive and multi-dose vaccine, in which they contribute to its wastage. And these need special cold chain management and reduction doses in vial so as to reduce wastage. Some of the health centers did not use shake-test for some freeze sensitive liquid vaccines after frozen.

Regarding cost of vaccines, as shown in table 6, the most expensive vaccines and with average unit cost per dose was PCV (2.89USD), Rota (1.83USD), and Pentavalent (1.034USD) which two doses were single-dose vial vaccines respectively. The study showed that vaccines accounted for higher wastage rate were PCV (49,670.81USD) and Rota (10,408.9USD). The current study showed that the wastage of Measles and TT in terms of cost was 5,441.254USD and respectively 2,463.916 USD, which were lower than the done in India Measle (3,087,880USD), and TT (237,731USD) (Khonputsa, et al., 2017). The total vaccine wastage of the current study was 103,512.25USD. The previous study was done in Cameron assured that there was overall excess wastage of vaccines, i.e. 605.011 USD for routine and 591.05 USD for outreach in each health center. The wastage rate of pentavalent in the study in terms of cost was 5.96% which was lower than the study done in Cameron in which wastage rate of two doses pentavalent (72.7%) in both fixed. The overall wastage rate of the current study in monetary value 14.3% which lower than the previous study which had an overall wastage rate of 19.5 % from issued vaccine stock (Ebon and Levy, 2011). This indicated that multi-dose vial vaccines accounted for more vaccine wastage than single-dose vial vaccines.

Concerning the availability and applicability of policy and procedures, the study indicated that the health centers had manuals, guidelines for vaccine stock management (88%), written procedures for MDVP (81%), for VVM (81%), shake test (83.3%), for instruction preventive (PM) and curative maintenance was (85.7%) which were lower than the Ethiopian ministry of health and pharmaceutical supply agency training manual recommendation (FMOH and EPSA, 2018). A Study done in Cameron indicated that the presence of vaccine national guidelines in health centers was 66.1 %(Yakum, *et al*., 2015). A study was done in Africa

like the Gambia showed that the application of MDVP for TT, IPV, Polio were (68.75%), 62.5% and65%.respectively. whereas, the previous study for BCG (13%) and Measles (16.25%) were lyophilized and liquid vaccine respectively (Usuf, *et al.,* 2018). The health centers that were achieved an overall score on availability and applicability of policy and procedures were 79.2% which was higher than assessment don by Clinton health access initiative 60 % (CHAI, 2018). The poor availability and application of MDVP implied that there were facing of more vaccine wastage. The availability, sticking and application of the vaccine policy was important for reducing vaccine wastage.

Regarding training, the study showed that good training achievement in immunization practice and cold chain management; whereas training on stock management had poor achievement. The 52.3% per health workers for vaccine stock management 92.8% of the vaccinator took training on immunization practice and storage and cold chain management. But stock management was 52.3%. The study done in Mozambique showed that 59.6%) were ever attended training on storage, distribution and handling Procedures of cold chain medicines (Carlos, *et al.,* 2007). Since vaccines are expensive and temperature-sensitive products, all the health workers working in the EPI clinics should be trained application policy on cold chain management and handling temperature monitoring, vaccine stock management, application and stock recording of vaccines, otherwise, the vaccine faced to wastage (WHO, 2017).

Concerning the condition of refrigerator, the current study indicated that the number of health centers in Addis Ababa that had appropriate WHO standard refrigerators was 69 % (n=29) and functional fridge tag were 100% which was higher than the study done in Ethiopia like, Gurage zone both the availability of refrigerator 22.8% and fridge tag were 85.7%(Jemal, et al., 2019) But, it was lower than a study conducted in the north-west region of Cameroon in which 95.1% of health centers had functional refrigerator with a working thermometer(Yakum, *et al*., 2015). The study showed that 90.5% the facilities had enough storage temperature which was lesser than assessment done by Clinton health access initiative project in Ethiopia was 99% (CHAI,2017) and 82% of health centers effective vaccine assessment in Ethiopia (FMOH,2013) had adequate capacity to store vaccine. The previous study done in India showed that adequate storage capacity for vaccines was 92.8 % (Panika, *et al.,* 2018). Study in Bale southeast Ethiopia, 17.14% of health centers were stored in temperature readout of range of 2°C- 8°C which was above 8°C (Woldemicheal, *et al.,* 2018).

This was not in line with the WHO recommendation that the vaccines store with temperature 2°C -8°C (WHO, 2017).

There was evidence of 92.9% of health centers had dedicated or separated room for vaccine storage and immunization which was lesser than the study was done in India that 100% of the health facilities have separate space (Panika, *et al.*, 2018). It was observed that 83.3% health centers refrigerator door opening during immunization sessions was not minimized (two times a day) which were not inline of ministry of health, and WHO guideline recommendation (FMOH and PFSA, 2016) and (WHO, 2017), and the previous study also showed that, all the health centers opened and close refrigerator door money times of a day during immunization which resulted in the temperature reading was $+18C^0$ much above that required for vaccine storage(Carlos, *et al.,* 2007). Findings revealed that 64% of assessed sites had written preventive maintenance plans. There was visual evidence of maintenance activities observed in 65% of the sites (CHAI, 2017). The health centers that were achieved an overall score on conditions of refrigerators were 75.5% which was nearly the same as the assessment (FMOH, 2013). The condition and standard of refrigerator was important for vaccine handling. Otherwise, refrigerator without WHO and UNICEF standard, it could be exposed to more vaccine wastage.

Regarding the storage and cold chain management, the recent study indicated that all health centers had temperature recording sheet which were higher than the previous study done at northwest region of Cameroon, only 50% (n=26) of the health centers had a temperature monitoring chart (Yakum, *et al*., 2015) and 66.7% of the health facilities completed records of storage temperature at least twice daily for 7 days per week manually which were higher than the study done in selected area of Ethiopia which had completed record of refrigerator its temperature records taken twice a day were observed in 37 (59.8%) of the 64 functional immunization centers (Birhane, *et al.*, 2000). In the current study, 85.7% of the health centers had temperature reading record (hard copy) sheet similar to the temperature reading on the fridge tag, and 76.2% of health centers temperature motoring devices were placed in the center of the refrigerator in every direction which was lesser than the previous study 98% (Yakum, *et al*., 2015).

The finding of study declared that, 81% of the health centers did not store vaccines within the temperature of between 2 – 8ºC throughout the year and there were 71.4% of them only outside 2 – 8ºC response had been documented. A study done in three African countries like Ghana, Kenya and, Uganda, the health facilities stored vaccines outside the recommendation

temperature range were 26.2%, 16.3% and, 7.9% respectively with one instance time observation (Emily, et al., 2013). The study also showed that 26.2% of the facilities encountered with a freeze of vaccines and there were 11.3% of the facilities faced to damage vaccines due to freezing which higher than the previous study 5 %(Ashish, et al., 2012). The health facilities that were achieved an overall score on storage and cold chain management were 75.8 %% which was higher than effective vaccine assessment of 69% health facilities in Ethiopia (FMOH, 2013). The poor cold chain management resulted; because it could be caused by lack of training and presence of Sub-standard refrigerator. This implied that there were facing of more vaccine wastage.

Concerning the stock management and recording, the current study showed that there was evidence, 23(54.7%) of the health centers did not do physical inventory which may faced the health facilities to missing inventory which lesser than assessment done by Clinton health access initiative, Ethiopia, which was 61% of physical inventory (CHAI, 2018) and higher than 26.6% (FMOH, 2013). 14.5% of the health centers recorded the vaccine stock on bin card. There were evidence of 76.2% of the health facilities had overstock which lead to inappropriate storage and expiry of vaccine higher than the study health centers which was done in Bale zone southeast part of Ethiopia confirmed that the inappropriate arrangement of vaccines in refrigerators was not correct (Birhane, *et al.,* 2000). The studies conducted in Cameroon also showed that 78.6 % of the facilities overstocked (Yakum, *et al*., and 2015). The study also showed that 80.5% of the health centers administered according to the FEFO principle, there was evidence that 45.2% of the health centers had given the priority to VVM change than expiry during immunization. The recent study indicated that 16.7% of the health facilities did not have enough syringe for injectable vaccines and 23.6% of the facilities were not vaccine stock correspond its diluents.

The previous assessment of some regions of Ethiopia and UNICEF showed that there was a mismatch between vaccine and diluents at some woredas and service delivery levels (FMOH, 2013; UNICF, 2018). All the health centers did not report open vial wastage; in which only 52.4 % the health centers had closed vial vaccine wastage rate reports and 16.7% of the facilities did not monitor vaccine wastage. Based on effective vaccine management assessment tool, very few stores are recording wastage information and fewer are reviewing it to make use for improving the program (FMOH, 2013). The health centers that achieved an overall score on conditions of refrigerators were 56.8 % and were higher than the assessment of effective vaccine management 53% health facilities in Ethiopia (FMOH, 2013). Because it

could be caused by lack of training, and Poor stock management resulted in poor application of FEFO principles and failure of prioritizing VVM than FEFO. This implied that there were encounter of more vaccine wastage

Regarding the vaccine vial monitoring VVM, all facilities record vaccine VVM stage which was better than effective vaccine assessment in Ethiopia which stated that several records were not updated (FMOH, 2013). The study showed that 61.9% health centers documented that vaccines delivered with second VVM stage to the facilities which were changed immediately to non usable third stage (e.g. polio) in which immunization supply chain management strategy situational analysis supported this study by saying there were delays in delivery and near discarded point or near VVM stage delivery to health centers (FMOH and EPSA, 2018). There were 73.8% of the facilities experienced to damage vaccines due to VVM change which supported by the previous assessment findings revealed that 19% of health facility assessed do not use VVM for vaccine management (CHAI, 2018). The health facilities that were achieved an overall score on vaccine vial monitoring were 67.6 %% which was lesser than supported by the previous assessment findings revealed that 91% of health facility assessed use VVM for vaccine management (CHAI, 2018).

Concerning immunization practice, 23.8% of the health centers were fully labeled with the date and time of reconstituted vaccines wastage and was lower than the study done in Gambia 47.4 % (Usuf, et al., 2018). The study showed that there were discarded dose of lyophilized after the opening of vaccines within six hours. The study also indicated that 19% of the facilities discarded doses of liquid vaccines were after opening of vaccines within 28 days. There were also no vials of liquid vaccines before opening at time visit without vaccinating all dose within 28 days. The previous study which was done in Nigeria indicated that 84% of the health workers discarded the lyophilized vaccines and 47% of health workers discarded liquid vaccines (Wallace, et al., 2017). The health facilities that achieved an overall score on immunization practice were 80.3% % which were not according to Ethiopia Pharmaceutical vaccine and cold chain training manual (FMOH and PFSA 2016). Vaccine coverage is also one of the contributing factors for vaccine wastage.

7. Strength and Limitation of the study

7.1. Strength

The strength of the study was conducting of wastage rate of vaccines in health centers which was not done in academic area of Ethiopia, and which could be used as a base line in Addis Ababa city administration for forecasting of vaccines.

7.2. Limitation

For logistical reasons, the study was restricted to the health centers in Addis Ababa City Administration, which are relatively maintained vaccines stocked records for 12 months and above. Excluded hospitals, because hospitals did not have complete stock records during the study period. The findings of the study can therefore only be generalized to the health facilities which have similar organization/structure and services arrangements. The study also needs more time for data collection and analysis. The reliability of the records on the health centers may also affect the study.

8. Conclusion and Recommendation

8.1. Conclusion

The finding showed high vaccine wastage of lyophilized and open vial vaccines in most cases. A lyophilized vaccine-like BCG and measles accounted for more wastage than liquid vaccines. The wastage of open vial vaccine like BCG, Measles, IPV and TT wastage were higher than closed vial vaccine wastage. But, closed vial vaccine wastages rate of these vaccines were not fit according to of WHO's recommendation (1%). The finding showed that in terms of cost from total issued stock, the average wastage rate of all vaccines was 14.3%. Some Health Centers had inappropriate vaccine stock and cold chain management. Certain Health Centers did not give priority to the VVM stage than expiry during issuing the vaccine from the refrigerator. The major reason for vaccines wastage rate for measles and TT was expiry. Whereas for polio and BCG were the VVM change. The major cause of IPV wastage was freezing and major wastage rate of closed vial vaccine wastage expiry. The study also showed that the wastage rate of multi-dose vaccines was greater than the single-dose vial wastage. The health centers prepared and had sent reports of closed vial wastage rate to the concerned body, but not open vial wastage and the monitoring system of wastage rate. The major contributing factors for vaccine wastage were vaccine stock management, vaccine vial monitoring (VVM), storage and cold chain management. The lower vaccine wastage contributing factors were training and availability of policy and procedures. Generally, the health centers did not strictly apply the effective vaccine management.

8.2. Recommendation

Based on the findings of the study, the following recommendations were given as:-

1. The Health Centers should have an effective vaccine storage, stock, and cold chain management.
2. The Health Centers should give priority to both VVM stage and expiry during issuing the vaccine from the refrigerator.
3. All the Health Centers should apply multi-dose vial policy (MDVP) for reducing open vial vaccine wastage and should have efficient stock management to minimize closed vial vaccine wastage.
4. The Health Centers should have an effective wastage rate monitoring system for open vial vaccine wastage rates.
5. The country should import the lesser dose vial vaccine by considering cost-benefit analysis of the vaccine.

6. Studies should be conducted on the effect of vaccine wastage rate on the supply of vaccines and vaccination coverage of the Addis Ababa city administration.

Reference

AACAHB (2017). Addis Ababa City Administration Health Bureau plan versus achievement annual performance report.

AACAHB (2018). Addis Ababa City Administration Health Bureau achievement annual performance report.

AAU (2009). Introduction to research methods. Preparatory module for Addis Ababa University graduate programs. Graduate Studies and Research Office.

Ashish KN., Rupani MR., Bansal R. (2013). Evaluation of Vaccine Cold Chain in Urban Health Centers of Municipal Corporation of Surat City, Western India, *Int J Prev Med*, 4(12):1395-1401.

Bagdey P., Narlawar U., Surwase K., *et al* (2017). Assessment of Vaccine Wastage in Tertiary Care Centre of Central India. A Cross-Sectional Study; *Int.J.Health Sci. Res*,7(4): 12-17.

BursteinR., Dansereau EA., Conner RO., *et al*. (2013). Assessing vaccine cold chain storage quality: Across the Sectional study of health facilities in three African countries. The Lancet, 381 (S25): doi:https://doi.org/10.1016/S0140-6736 (13) 61279-9.

Carlos de J., Mavimbe M.,Bjune G.,et al (2007). Cold chain management: Knowledge and Practices in Primary health care facilities in Niassa, Mozambique [Ethiop.J.Health Dev 21(2):130-135

CHAI (2017). Vaccine Management baseline assessment report using adopted tool in Ethiopia, Clinton Health Access Initiative Ethiopia Vaccine program, https://clintonhealthaccess.org/content/uploads/2018/10/2017-Annual-Report-.pdf.

Chinnakali V., Kulkarni V., Kalaiselvi S., Nongkynrih B.(2012). Vaccine wastage assessment in a Primary care setting in urban India. *Journal of Pediatric Sciences*, 4(1): e119.

Drain PK., Nelson SM., Lloyd JS. (2003). Single-dose versus multi-dose vaccine vials for immunization programs in Developing countries, Bull World Health Organization, 81 (10): 726-731.

Ebon CE. Levy P., (2011). Impact of the introduction of new vaccines and vaccine wastage rate on the cost-effectiveness of routine EPI: Lessons from a descriptive study in a Cameroonian health district, Cost Effectiveness and Resource Allocation, 9:9 http://www.resource-allocation.com/content/9/1/9.

Emily RB.,Conner D.,Censo DS., et al (2013).Assessing vaccine cold chain storage quality of Health Facilities in three African Countries: Across Sectional study *Institute for Health Metrics and Evaluation,* University of Washington, Seattle, WA, USA; Published Online June 17: 2013

EPSA (2017). Ethiopian Central Statistics Agency projected annual population growth.

EFMHACA (2016). Guideline for Surveillance and Response to Adverse Events Following Immunization, Ethiopian Food Medicines, and Health Care Administration and Control Authority (EFMHACA), 2nd Ed., Addis Ababa.

FMOH and PFSA (2016). Federal Ministry of Health of Ethiopia and Pharmaceutical Fund supply agency: Vaccine and cold chain management training manual, Module 6.

FMOH (2013). Federal Ministry of Health of Ethiopia: Assessment of effective Vaccine Management assessment; August.

FMOH (2018). Federal Ministry of Health of Ethiopia: Annual performance report.

FMOH (2016), Ethiopian Federal Ministry of health Immunization in practice training manual for health workers.

FMOH and EPSA (2018). Federal Ministry of Health of Ethiopia and Ethiopia Pharmaceutical Supply Agency: Immunization Supply Chain Management Strategy Ethiopia.

Gupta V., Mohapatra D., Kumaret V., (2015*).* Assessment of vaccine wastage in a tertiary care centre of Rohtak, Haryana, *Ntl,. J. Community Med.,* 6 (3): 292-296.

Goldwood G., DiesburgS. (2018). The effect of cool water packs preparation on vaccine vial temperatures in refrigerators, Vaccine, 36 (1): 128-133.

Jemal ZY., Yimer HN.,Tariku BD., *et al* (2019). Knowledge of Health Professionals on Cold Management and Associated Factors in Ezha District, Gurage Zone, Ethiopia, Hindawi Scientific Volume; Article ID 6937291, page, shttps://doi.org/10.1155/2019/6937291

Khonputsa P., Plewes K., Nicholas PJ., Lubell Y., (2017). Cost, health impacts and cost-effectiveness of iceless refrigeration in India's vaccine cold chain. Center for Tropical Medicine and Global Health, University of Oxford https://www.technet-21.org/images/tc2017/Posters/MORU_Costeffectiveness_ice_based_chold_chain_TechNet.pdf.

Meleko A., Geremew M., Birhanu F., (2017) Assessment of Child Immunization Coverage and Associated Factors with Full Vaccination among Children Aged 12–23 Months at Mizan, Aman Town, Bench Maji Zone, and South west Ethiopia*: Int. J. Pedi. 2017: https://doi.org/10.1155/2017/7976587*

NMOH (2012).Guidelines for Vaccine Storage and Distribution. [Online] Available:http://www.immune.org.nz/sites/default/files/factsheets/Vaccine- Storage Guidelines,pdf.

Okwaraji BY., Andarge G, Admasu M. (2012). The association between travel time to Health Facilities and childhood vaccine coverage in rural Ethiopia. A community based Cross sectional study: Faculty of Epidemiology and Population Health, London, School of Hygiene &Tropical Medicine, London, UK: http://www.biomedcentral.com/1471-2458/12/476

PanikaRK ., Gupta A. (2018). Assessment of cold chain and logistics Management practices: Across Sectional study in Bundelkhand region of Madhya Pradesh *Int J Community Med PublicHealth,* 5(12):5143-5149.

Patle L., Adikane H., Dhage D., Surwase K., Gogulwar S. (2017). A Cross Sectional Study of Vaccine Wastage Assessment in a Primary Health Care Setting in Rural Central India, *Sch. J. App. Med. Sci.,* 5(8F): 3411-3415.

PFSA (2014). Ethiopian Pharmaceuticals Supply Chain Management System Monitoring and Evaluation Training Manual.

Ringo S., Mugoyela V., Kaale E., Sempombe J. (2017). Assessment of medicines Cold Chain Storage Conformity with the World Health Organization Requirements in Health Facilities in Tanzania, *Pharmacology & Pharmacy*, 8:325-338.

Rittle C., Childre F. (2008). Maintaining vaccine effectiveness in Occupational Health Clinics, *AAOHN J*, 56(7):277-279.

Sharma G., Sethia R., Acharya RS., Meena RR. (2016) Assessment of vaccine wastage in the immunization clinic attached to S. P.Medical College, Bikaner, and Rajasthan, *Int J Community Med Public Health*, 3(3):675-678.

Tiwari R., Dwivedi S., Swami P., Mahore R., Tiwari S., *(*2017). Study to assess vaccine wastage in an immunization clinic of tertiary health care center, Gwalior, Madhya Pradesh, India, Int *J Res Med Sci*., 5(6): 2472-2476.

UNICEF (2010). Field assessment and observations from national stores and five selected states of India: UNICEF; Available at:http://www.unicef.org/india/vaccine _wastage Assessment India.pdf.

UNICEF (2018). Ethiopia: Country Office Annual Report-Part 1: Situation update in the country, available at: https://www.unicef.org/about/annualreport/

UNICEF (2017) Vaccine and injection safety price list available for Global alliance vaccine Initiatives (GAVI).Cost available to low income and GAVI supported countries: https:// www.unicef.org/supply/topics/vaccines?items_per_page=All.

USAID | DELIVER PROJECT (2011). *The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities*: USAID | DELIVER PROJECT, Task Order 1a.

USAID| DELIVER PROJECT (2011). Guide to Conducting Supply Chain Assessments Using the LSAT and LIAT. USAID | DELIVER PROJECT, April, Task Order1b.

Usuf E., Mackenzie G., Ceesay L., Sowe D., Kampmann B., Roca A.(2018). Vaccine wastage in the Gambia. Prospective observational study; *BMC Public Health,* 18:864.

Wallace AS., Willis F., Nwaze E., *et al* (2017). Vaccine wastage in Nigeria: An assessment of Wastage rates and related Vaccinator Knowledge, Attitudes and Practices, *Vaccine. 35 (48 Pt B): 6751-6758.*

WHO (2005a).Monitoring Vaccine Wastage at country level: guidelines for program managers, World Health Organization, https://apps.who.int/iris/handle/10665/68463.

WHO (2014). WHO policy statement: multi-dose vial policy (MDVP): handling of multi-dose vaccine vials after opening World Health Organization: https://apps.who.int/iris/handle/10665/135972.

WHO (2010). Policy Statement: The use of opened multi-dose vials of Vaccine in Sub-sequent Immunization sessions. WHO Document WHO/V&B/00.09 :www.who.int/vaccines documents/Docs.PDF99/www9924.Pdf.

WHO (2005b). Vaccine management assessment tool and guidelines: Department electronic research of Immunization*V*accine and Biological, Geneva, Switzerland: https://apps.who.int/iris/handle/10665/69165.

WHO (2017). Mid-Level Management Course for EPI Managers: Block III: Logistics: Module 8: Vaccine management. World Health Organization, Regional Office for Africa https://apps.who.int/iris/handle/10665/260479.

WHO (2015). How to monitor temperatures in the vaccine supply chain: WHO Vaccine Management Handbook Module VMH-E2, Department of Immunization, Vaccines and

Biologicals,Geneva:http://apps.who.int/iris/bitstream/10665/183584/1/WHO_IVB_15.03_eng.pdf.

WHO (2018).Summary of WHO Position Papers: Recommendations for Routine Immunization, https://www.who.int/immunization/policy/Immunization_routine_table1.pdf.

Woldemicheal B., Bekele D., Esmael A. (2018). Cold Chain Status and Knowledge of Vaccine Providers at Primary Health Care of Units Bale Zone, South East Ethiopia: *Immunome Res.*, 14:15, DOI: 10.4172/1745-7580.1000152.

Yakum MN., Ateudjieu J., Walter EA., Watcho P. (2015). Vaccine storage and cold chain monitoring, Cameroon: A Cross sectional Study. BMC Research Notes, 8:145, DOI 10.1186/s13104-015-1109-9.

Yang W., Parisi M., Lahue BJ., Uddin M., Bishai D. (2014). The budget impact of controlling wastage with smaller vials: A data driven model of session sizes in Bangladesh, India (Uttar Pradesh),Mozambique, and Uganda, Vaccine, 32(49): 6643-8.

Yassin ZJ., Nega HY., Derseh BT., Yehuala YS., Dad AF.(2019). Knowledge of Health Professionals on Cold Management and Associated Factors in Ezha District, Gurage Zone, Ethiopia, *HindawiScientifica*https://doi.org/10.1155/2019/6937291

Annexs

Annex I

Data Collections Tools for vaccine Wastage and contributing Factors in selected health centers of Addis Ababa, Ethiopia.

Vaccine wastage and contributing factors

Introduction and Consent

Verbal consent form

Good morning/afternoon. My name is _____.

Thank you for taking the time to talk with me. 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 wastage and contributing factors in Health centers of Addis Ababa, Ethiopia". If you agree, I will be asking you questions about your experience on immunization and immunization supply chain. We are interested in finding out what health workers think particularly vaccine wastage and contributing factors. This information will be used to help know quality immunization supply chain and services for children and pregnant women in Addis Ababa city.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.

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. You may also stop the interview at any time. It will take about a day and half for both interview and data extraction for us to complete the questionnaire. Do you have any questions about the study? If in case should you have any questions about the study in the future, please feel free to contact the Addis Ababa University and Addis Ababa Health Bureau or the research team leader Mr.TesfahunTawy

_____ _____

Signature of person administering consent Date

Annex II

Questionnaires

Vaccine and vaccine management

Name of health facility…….

If client refuses to be interviewed, please check this box:

001 Sub-city ----------

002 Health center ----------

003 Name of Interviewer ----------

Time interview began: _____: _____ ☐

Hours Minutes

	Question – Vaccine and cold chain management	Options	
1	Demographic information	Circle ones	Remarks
1.1	EPI focal person	1. Male 2. Female	Interview
	Age	a.20-30 b.31-41 c. >41	Interview
1.4	Education/profession	Pharmacy Junior Nurse Senior nurse	Interview

		BSc nurse Health Officer	
1.5	Unit/Section	Pharmacy EPI unit Cold chain	Observation
1.6	Service year in health profession	_____ Year	Interview
1.7	Service year in EPI /immunization supply chain	_____ Year	Interview
1.8	Training you have taken so far	• IIP • Immunization supply chain • Cold chain • Trained individual responsible for stock recording	Interview and Observing the Certificate
	Basic information		
1.9	How many numbers of functional Refrigerators? Is it solar or kerosene or electric? (Write on remark)		Observation

1.10	How many numbers of functional cold boxes? (Write on remark)		Observation
1.11	How many numbers of functional vaccine carrier? (Write on remark)		Observation
1.12	How many numbers of functional icepack? (Write on remark)		Observation
1.13	How many numbers of functional vaccines carriers with foam pad? (Write on remark)		Observation
1.14	a. How money under 1 year children? b.Immunization coverage		Document review (plan)
1.15	Have you taken any training refresher in the last 12 months, if yes please list them	Yes, _____ No____	Interview
S.NO	Questions	Response If Yes =1 If No = 0	Remark
2.	Policy ,procedures and guideline		
2.1	Policies, procedures and guidelines available for vaccine management.		Observation
2.2	Is there evidence of the health facility has been adopted and applicable MDVP? Is there Written Procedures?		Observation
2.3	Is there evidence of written instruction preventive maintenance (PPM) cold chain equipment available?		Observation
2.4	Do have written procedures used for shake test for frozen Vaccine (IPV, PCV or TT)?		Observation
2.5	Are written instructions on the use of vaccine vial monitoring (VVMs)?		Observation
2.6	Are opened vials of freeze-dried vaccines discarded within six hours of		Observation

	reconstitution, at the end of each immunization session?		
2.7	Are opened vials of liquid vaccines kept for the next immunization sessions within 28 days?		Observation
2.8	Is there evidence of written instruction for curative maintenance cold chain equipment		Observation
3	Stock management		
3.1	Stock cards/ledger book for vaccines are kept.		Observation
3.2	Does the EPI room have stock/bin cards?		Observation
3.3	Stock /bin cards for vaccines are correctly filled in.		Document review
3.4	Is there evidence of recording records of Beginning balance, ending balance, receipt, issued and used of vaccine in ledger book?		Document review
3.5	Are discarded, dose presentation of vaccine and diluents and children vaccinated recorded in ledger book and others?		Document review
3.6	Is there of evidence of vaccines expiry date recorded		Document review
3.7	Is there evidence of physical inventories of vaccine stock?		Document review
3.8	Is there evidence of maximum stock level (over stock)? (write type of vaccines)		Document review
3.9	There are times when vaccines are over stock(write the vaccines)		Document review
3.10	Are there vaccine wastage reports available?		Document review
3.11	Is there a vaccine wastage monitoring system? Review reporting forms that are used to Monitor vaccine wastage.		Document review

3.12	The first in first out principle applies when issuing and using vaccines		Document review (using receiving and issuing date) and observation
3.13	Is vaccine distribution (administered) generally made according to the "first expiry – first out" (FEFO) principle only?		Document review
3.14	Is the vaccine administered using both first expiry – first out and first in first out principle only?		Document review (using, expiry, receiving and issuing date)
3.15	Liquid/open and unused vaccines returned at the end of vaccination session (TT, polio, and IPV)		Observation
3.16	Does the vaccinator give the priority to VVM change than expiry during immunization?		Document review
3.17	Are sufficient syringes, needles and sharps containers available for immunization session?		Document review(number of doses and syringes)
3.18	Does the vaccine stock correspond with the diluents stock?		Document review(number of doses and diluents)

3.19	Is there evidence of expired vaccines in the facility?(write the vaccines)		Document review(Observation)
3.20	Is there evidence of broken vaccines in the facility?		Document review
3.21	Number facilities of that had inventory missed vaccines		Document review
5	Condition of the refrigerator, is situated in a well-ventilated area.		
5.1	The refrigerator type is appropriate for vaccines (WHO, and UNICFE standard).(is it electrical, model TCW 1152,TCW1990,MF 114,MF 214,MF 314,MK 204,TCW 3000…etc)		Observation
5.2	The refrigerator adequate capacity to store adequate vaccines or storage volume. • (Required Storage Volume in liters = Net volume per fully immunized child (0.122 lit) x Number of children under 11 months x Immunization coverage target and • Required Storage Capacity = Vaccines Storage Volume X Equipment Volume Factor)		Observation (Observe after calculation based on the standard)
5.3	Vaccines are stored near or on the door		Observation
5.4	Food or cool drinks are stored in the same refrigerator that is used to store vaccines.		Observation
5.5	The refrigerator is lockable and locked?		Observation
5.6	Refrigerator door opening during immunization sessions is minimized (two times a day).		Observation
5.7	Due to Interruption electric power, faced refrigerator failure		Document review

5.8	The Health facility has a back-up system in case of power failure (contingency plan).		Observation(contingency plan)
5.9	Is there evidence of dedicated or separated room for vaccine Storage and immunization?		Observation
4510	The refrigerator is correctly packed with air circulating between the vaccines.		Observation
5.11	Is there evidence of preventive maintenance (PPM) and curative maintenance to cold chain equipment available?		Document review
6	Storage and Cold chain management and temperature monitoring		
6.1	Is there evidence vaccine refrigerators temperature recording sheet?		Document review
6.2	Is there evidence that the EPI (Refrigerator) room have fridge tag and functional?		Observation
6.3	A working temperature motoring device (RTMD, fridge tag) placed in the centre of the refrigerator.		Observation
6.4	Is there a complete record at least twice daily and for 7 days per week manually?		Document Review
6.5	The refrigerator has an alarm which is activated when the temperature exceeds8 degrees Celsius (8ºC) and falls below 2 degrees Celsius (2ºC).		Document Review(or See fridge-tag)
6.6	Is the refrigerator temperature between (2 - 8ºC) throughout the year?		Document Review
6.7	The responses to all deviations outside (2 - 8ºC) have been documented		Document Review

6.8	Is the cold boxes/vaccine carrier available and in a good condition?		Observation
6.9	Are ice packs conditioned before use?		Observation
6.10	Is the temperature reading record (hard copy) sheet similar to the temperature reading on the fridge tag (check all alarms and reading)		Document Review
6.11	Is there evidence of presence of refrigerator thermometer?		Observation
6.12	Dos the facilities faced freezing of vaccine?		Document Review
6.13	Is their evidence of shake test for frozen vaccines?		Document Review
6.14	Is there evidence of damaged vaccines due to freezing in the facility? (write the vaccines)		Document Review
7	Vaccine vial monitoring (VVM)		
7.1	Is vaccine distributed (administered) generally made according to the VVM status? See the administered and other vaccines.		Observation
7.2	vaccine deliver with second VVM stage(VVM stage two) to the facilities(name of vaccine)		Document Review
7.3	Is vaccine VVM stages recorded?		Document Review
7.4	Vaccines are used when VVM stage is one and two.		Document Review
7.5	Evidence of damaged vaccines due to VVM change in the facility(write the vaccines)		Document Review

8	Immunization practice		
8.1	Two or more vaccines mixed in the same syringe during the immunization session.		Observation
8.2	Reconstituted vaccines are fully labeled with the date and time.		Observation
8.3	Vial size or vial presentation has contribution to vaccine wastage.		Observation
8.4	Contamination (submerged in water) of vaccines.		Observation and see records
8.5	The discarded dose of BCG and Measles after opening of vaccines within 6hrs.		Observation(see labeling)
8.6	The discarded dose of liquid vaccines after opening of vaccines within 28 days.		Observation(see labeling)
8.7	Health centers not administer lyophilized vaccines without fixed schedule.		Observation
8.8	Health centers have practices of client reaction requiring more than one dose		Observation
8.9	Not being able to draw the number of dose (write type of vaccines)		Observation

Annex III

Data abstraction format for vaccine wastage

Performance of the vaccination in terms of vaccine stock----------

Name of the vaccine	Presentation of Dose (dose per vial)	No. dose per fully vaccinated children	Beginning balance(Dose)	Received Dose	Used dose	Transferred dose	Dose discarded due to expiry	Dose discarded due to VVM Change	Dose discarded due to freezing	Discarded Dose contaminated, Broken, inventory missing.	Total Discarded Dose (Unopened)	Ending balance(Dose)	No. of children vaccinated in the study period	Immunization Coverage	Unit cost	Remark
Oral Polio	10	4														
Oral Polio	20															
Measles	10	1														
BCG	20	1														
DPT-HepB-HiB	1	3														
PCV	2	3														
Rota	1	2														
IPV	10	1														
TT	10	2														
TT	20															

Vaccine stock information – Retrospective data, from May/ 2018 to April /2019(n=42).

Annex IV. List of the Health centers

S.No	Name of Health facilities	Sub-city	Number of health facilities	Remark
1	Addis ketema health center	Addis ketema	4	
2	Woreda 7 health center			
3	Ginbot 20 health center			
4	Abebe Bikila health center			
5	Shiromeda Health center	Gullele	4	
6	Selam Health center			
7	Gutomeda Health center			
8	Entoto fana Health center			
9	Arada Health center	Arada	4	
10	Aboare Health center			
11	Beata Health center			
12	semen Health center			
13	Kebena Health center			
14	Bole 17 Health center	Bole	5	
15	Summit Health center			
16	Goro Health center			
17	Meri Health center			
18	Bole 17/20 Health center			
19	kasanchis Health center	Kirkose	3	
20	Meshualekia			
21	Kirkose Health center			
22	yeka Health center	Yeka	7	
23	Woreda 11 health center			
24	cheffee Health center			
25	Kotebe Health center			
26	Entoto no 1 Health center			
27	Woreda 1 health centers			

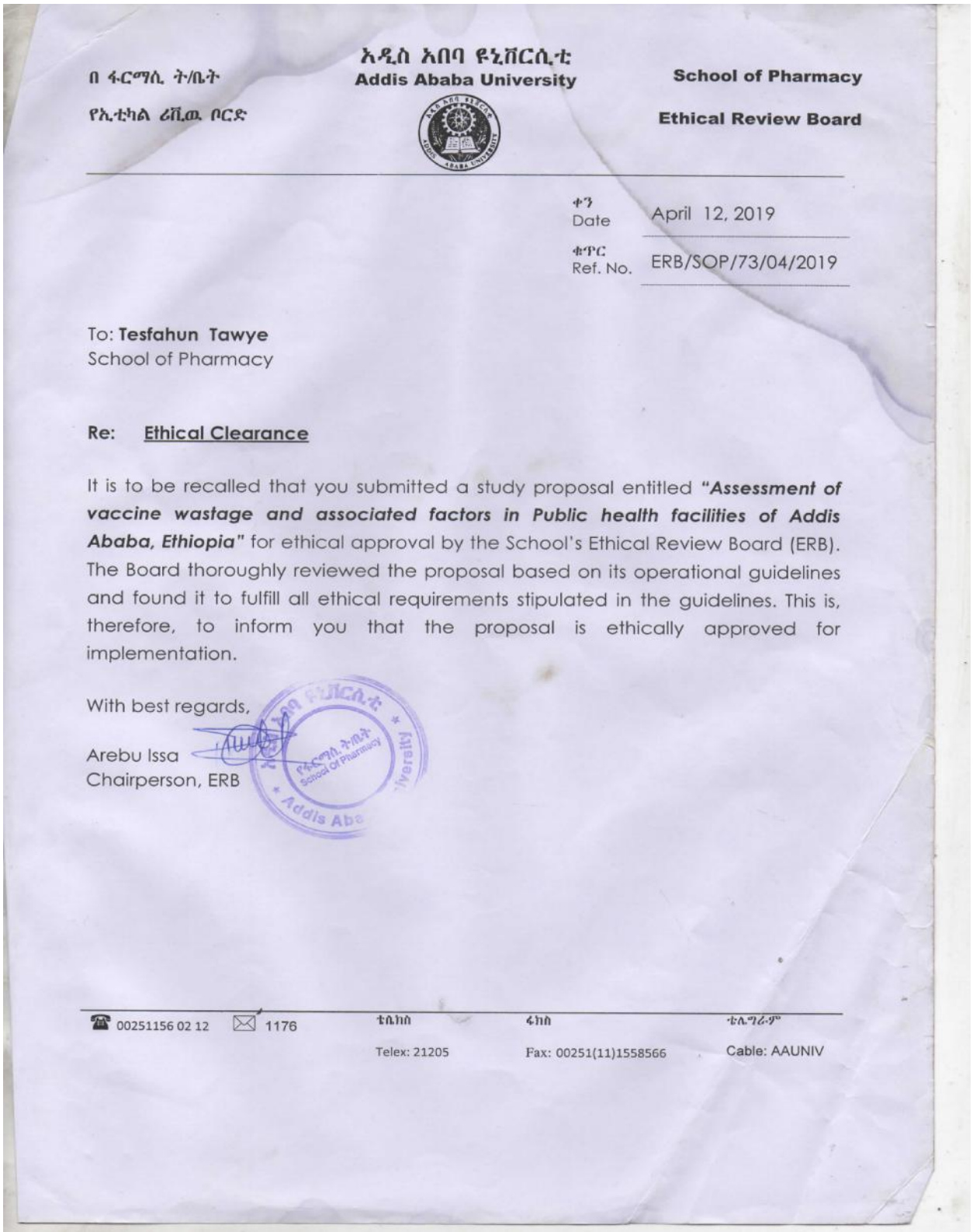
28	Woreda 7 Health center			
29	Woreda 1 Health center	Nifasilik	4	
30	Woreda 3 Health center			
31	Woreda 5 Health center			
32	Woreda 6 Health center			
33	Lideta Health center	Lideta	2	
34	Beletishachew Health center			
35	Kolfe Health center	Kolfe keraniyo	4	
36	Lomimeda Health center			
37	Woreda 9 Health center			
38	Woreda 8 Health center			
39	Saris Health center	Akaki kality	4	
40	Gelan Health center			
41	Akaki Health center			
42	Selam fire Health center			

V. Coverage of immunization in selected Health centers

Health centers	Coverage							
	Measles	BCG	Penta	PCV	Polio	IPV	Rota	TT
1	98%	95%	145%	145%	120%	71%	98%	75%
2	65%	86%	128%	130%	120%	68%	87%	71%
3	70	93%	95%	95%	89%	65%	89%	66%
4	65%	85%	71%	73%	86%	71%	67%	75%
5	84%	94%	102%	105%	120%	67%	102%	88%
6	92%	96%	129%	140%	120%	75%	95%	94%
7	69%	86%	97%	99%	93%	68%	87%	71%
8	92%	98%	135%	135%	116%	65%	101%	76%
9	86%	93%	99%	99%	88%	67%	87%	86%
10	66%	84%	87%	83%	90%	78%	85%	67%
11	67%	85%	77%	75%	76%	77%	83%	69%
12	75%	86%	118%	123%	100%	68%	87%	71%
13	70%	93%	115%	115%	125%	64%	89%	66%
14	74.9%	85%	71%	73%	76%	71%	67%	75%
15	85%	95%	103%	105%	102%	67%	87%	88%
16	88%	95%	129%	131%	105%	71%	98%	75%
17	67%	86%	100%	111%	99%	68%	87%	71%
18	70%	93%	100%	100%	98%	67%	89%	66%
19	86%	91%	96%	97%	76%	67%	65%	75%
20	84%	94%	98%	100%	101%	67%	102%	88%
21	88%	99%	128%	130%	130%	71%	98%	75%
22	99%	95%	138%	133%	105%	78%	87%	86%
23	70%	93%	101%	103%	115%	64.5%	89%	66%
24	67%	89%	73%	75%	79%	73%	67%	75%
25	89%	94%	102%	105%	98%	67%	102%	88%
26	70%	87%	83%	84%	89%	68%	79%	75%
27	75%	86%	108%	113%	103%	68%	87%	71%

28	70%	93%	105%	105%	99%	64%	89%	66%
29	78	85%	71%	73%	76%	71	67	75
30	65%	86%	108%	113%	96%	68%	87%	71%
31	72%	93%	106%	107%	115%	64%	89%	66%
32	64%	85%	71%	73%	76%	71%	67%	75%
33	70%	93%	105%	105%	115%	64%	89%	66%
34	80%	86%	72%	74%	77%	72%	68%	75%
35	88%	93%	102%	105%	111%	67%	102%	88%
36	84%	95%	128%	130%	130%	71%	98%	75%
37	65%	86%	125%	111%	99%	68%	87%	71%
38	84%	94%	122%	105%	111%	67%	102%	88%
39	78%	85%	71%	73%	76%	71%%	67%	75%
40	84%	87%	102%	105%	101%	67%	102%	88%
41	88%	91%	128%	130%	130%	71%	98%	75%
42	65%	86%	108%	113%	123%	68%	87%	71%
Cumulative percentage	84%	88%	100.2 %	101%	104%	67%	85%	75%

Annex VI. Ethical clearance letter from Addis Ababa University



አዲስ አበባ ዩኒቨርሲቲ
Addis Ababa University

በ ፋርማሲ ት/ቤት
የኢቲካል ሪቪው ቦርድ

School of Pharmacy
Ethical Review Board

ቀን Date: April 12, 2019

ቁጥር Ref. No.: ERB/SOP/73/04/2019

To: **Tesfahun Tawye**
School of Pharmacy

Re: **Ethical Clearance**

It is to be recalled that you submitted a study proposal entitled ***"Assessment of vaccine wastage and associated factors in Public health facilities of 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

ፋርማሲ ት/ቤት School of Pharmacy

00251156 02 12 | 1176 | ቴሌክስ Telex: 21205 | ፋክስ Fax: 00251(11)1558566 | ቴሌግራም Cable: AAUNIV

Annex VII. Ethical clearance letter from Addis Ababa city Administration Health bureau.

አዲስ አበባ ከተማ አስተዳደር ጤና ቢሮ

City Government of Addis Ababa Health Bureau

Ref.No. [illegible]

Date 2/8/2011

- Ghandi memorial hospital
- Zewuditu memorial hospital
- Addis ketema health center
- Woreda 3 health center (Addis Ketema SC)
- Ginbot 20 health cente (Addis Ketema SC)
- Kotebe Health center
- Entoto no 1 Health center
- Aboare Health center
- Ento to no 2 Health center
- Woreda 1 Health center (Nifasilik SC)
- Akaki Health center
- Selam fire Health center
- Woreda 3 Health center (Nifasilik SC)
- Woreda 5 Health center (Nifasilik SC)
- Woreda 7 Health center (Nifasilik SC)
- Shiromeda Health cente (Gullele SC)
- Abebe Bikila health center (Addis Ketema SC
- Selam Health center(Gullele SC)
- Gutomeda Health center (Gullele SC)
- Lideta Health center
- Beletishachew Health center
- Kolfe Health center
- Lomimeda Health center
- Entoto fana Health center (Gullele SC)
- Arada Health center (Arada Sc)
- cheffee Health center
- semen Health center(Arada SC)
- Kebena Health center (Arada SC)
- Bole 17 Health center
- Summit Health center
- Goro Health center
- Meri Health center
- Bole 17-20 Health center
- kasanchis Health center
- meshualekia HC
- Kirkose Health center
- Woreda 3 Health center (Kolfe keraniyo SC)
- Woreda 1 Health center (Kolfe keraniyo SC)
- Saris Health center
- Gelan Health center
- yeka Health center
- Yekatit medical college hospital

Addis Ababa

Subject: Request to access Health Facilities to conduct approved research

This letter is to support **Tesfahun Tawye** is to conduct research, which is entitled as **"Assessment of vaccine Wastage and Associated Factors in Public Health Facilities of Addis Ababa, Ethiopia."** 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 Health facility and staffs to provide support to the Principal investigator.

With Regards

Dr. Yohannes W/Kidan

Ethical Clearance committee

Cc

- **Tesfahun Tawye**
- **Ethical Clearance Committee**

Addis Ababa