



CHALLENGES OF COVID-19 VACCINE COLD CHAIN MANAGEMENT PRACTICES  
AND VACCINE UTILIZATION IN SELECTED GOVERNMENTAL HEALTH FACILITIES  
UNDER ADDIS ABABA REGIONAL HEALTH BUREAU

By

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Challenges of COVID-19 vaccine cold chain management practices and vaccine utilization  
selected governmental health facilities under Addis Ababa Regional Health Bureau

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## Declaration

I **Betelhem Endale** under signed, declare that this study entitled “*Challenges of covid-19 vaccine cold chain management practices and vaccine utilization in selected governmental health facilities under Addis Ababa Regional Health Bureau*” is my original work has not been presented any other university, and all source in the study have been fully acknowledged.

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## Certification

This to certify that **Bethlehem Endale** has carried out her thesis has been submitted to Addis Ababa University Department Health Supply Chain Management of for examination with my approval as a university advisor.

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The researcher

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## List of acronyms and abbreviation

**CDC**-Communicable Disease Control

**CHAI**-Clinton Health Access Initiative

**COVID-19**-Corona Virus Disease of 2019

**DTR**-Daily Monitoring Recording

**DTP**- Diphtheria, Tetanus Toxoids and Pertussis

**EPI**- Expanded Program on Immunization

**EUA**-Emergency Use Authorization

**FDA**-Food Drug Administration

**FMOH**- Federal Ministry of Health

**LIAT**-Logistic Indicator Assessment Tool

**MERS**- Middle East respiratory syndrome

**PATH**-Program for Appropriate Technology in Health

**PCV**- Pneumococcal Conjugate Vaccine

**PQS**-Product, Quality and Safety system

**SARS**- severe acute respiratory syndrome

**TMS**-Temperature Monitoring Studies

**UNICEF**-United Nations International Children's Emergency Fund

**VVM**- Vaccine Vial Monitors

**WHO**- World Health Organization

## Abstract

*The COVID-19 pandemic is causing unprecedented or extraordinary human and economic costs in all countries and societies across the world. After the WHO declared COVID-19 to be an international public health emergency vaccines were manufactured within one year. The Purpose of the study was to assess COVID-19 vaccine cold chain practice, challenges of cold chain management practices and vaccine utilization in selected government health facilities under the Addis Ababa Health Bureau. Both quantitative and qualitative research approach were employed. The population of the study was EPI focal persons who work in health facilities under 47 which accounts (44 health centers and 3 hospitals) and questionnaires were used to collect data and secured 95% response rate. Challenges of cold chain practice and utilization were filled using the five point likert scale and questionnaire was coded and analyzed using SPSS-V-20. Descriptive statistics mean were under taken regarding on cold chain capacity, stock management and vaccine storage temperature practiced slightly but regarding to cold chain equipment highly practiced. Furthermore, cold chain management challenges are influential in insufficient cold chain capacity, lack of latest technology or standard vaccine fridge, inadequate temperature monitoring and maintenance system, knowledge gap of health workers on cold chain practice as dependent variable.*

*For COVID-19 vaccines cold chain management practice: AACAHB, Sub city offices and other stakeholders should improve practice in storage capacity should be assessed and assign experienced cold chain equipment maintenance technicians at the facility level. COVID-19 vaccines require special storage temperature monitoring and stock management by using introduction of temperature monitoring and by identify and address logistical issues such as the distribution of adequate storage equipment and give training should be provided periodically to improve stock management and minimize wastage of vaccine.*

*Key words: Challenges cold chain management practice, COVID-19 vaccine practice*

# CHAPTER ONE

## 1. INTRODUCTION

*This chapter contains background of the study, statement of the problem, research question, significance of the study, objective of the study, definition of terms scope of the study and organization of the study.*

### 1.1. Background of the study

The COVID-19 pandemic is causing uncommon human and economic costs in all countries and societies across the world. It causes 2 million deaths and more than 88 million confirmed corona virus cases have been reported in world within one year. In Ethiopia there are 369,437 confirmed cases of COVID-19 with 6647 deaths reported in one year (WHO, 2019 and WHO, 2021a).

World Health Organization (WHO) gives COVID-19 name by on February, 11 2020. It emerges in Wuhan, China for the first time in late 2019 and spread worldwide. Virus caused by the SARS-CoV2 virus. It (COVID-19) is an acronym that stands for corona virus disease of 2019.

The following three human corona viruses cause much more serious infections such as SARS-CoV in 2002 (severe acute respiratory syndrome or “SARS”), MERS-CoV in 2012 (Middle East respiratory syndrome or “MERS”), and SARS-CoV2 (WHO, 2021a).

This infections are occur by different kinds of variant of corona virus the first variant is alpha Variant (B.1.1.7)strain of the SARS-CoV-2 variant that occur in the United Kingdom in September 2020 and then in many countries, with increased transmissibility, hospitalizations, and deaths.

Beta Variant (B.1.351)is the second strain of the SARS-CoV-2 variant known as B.1.351 that occur in South Africa in December 2020 with increased transmissibility, but minimal changes in hospitalizations and deaths.

Third variant is delta Variant (B.1.617.2) the strain of the SARS-CoV-2 virus known as B.1.617.2 that occur in India in May 2021 with increased transmissibility, hospitalizations, and deaths. The forth one is omicron Variant (B.1.1.519)strain of the SARS-CoV-2 virus known as B.1.1.529 that occur in South Africa in November 2021 with increased transmissibility, but likely decreased hospitalizations. (Relief central corona virus guideline,2021).

After the World Health Organization declared COVID-19 to be an international public health emergency COVID-19 vaccines were manufactured. (Glanville D, 2021).

A number of Covid-19 vaccine (259) were ongoing projects to develop effective and reliable vaccines in the world (Haider MF *et al*, 2021 & Mullard A., 2020) but only Sinovac Corona Vac, Moderna, pfizer/BioNTech, Janssen (Johnson & Johnson), Oxford/AstraZeneca, Serum institute of India Covishield (Oxford/Astrazeneca formulation), Bharat Biotech Covaxin, Sinopharm (Beijing) BBIBP-CorV (Vero Cells) are approved for use by WHO. (WHO, 2021b).

Pfizer-BioNTech and the Moderna COVID-19 vaccine issued an Emergency Use Authorization (EUA) by FDA in December 2020, and the Janssen COVID-19 Vaccine in February 2021, the Centers for Disease Control and Prevention (CDC) provided details of vaccination and authorized and recommended for their use in the United States of America and. Besides, Pfizer- BioNTech COVID-19 vaccine recommended for use in 12- through 15-year-old adolescents by CDC in May 2021 (CDC, 2021a).

The Ministry of Health of Ethiopia launched COVID-19 vaccine introduction in a high-level national event held at Eka Kotebe Hospital where frontline health workers were vaccinated to mark the beginning of the vaccination campaign. The first shipment of the AstraZeneca vaccines was arrived in Ethiopia on 6 March 2021 it produced by Serum Institute of India. (WHO, 2021c).

COVID-19 vaccine needs a cold chain which is a system for keeping the potent state of vaccine from at the manufacturing firm, including the transport and delivery of vaccines and correct storage at the provider facility and ends with administration of the vaccine to the client to ensure that vaccines remain potent from point of manufacture to administration (WHO, 2006). The cold chain guideline recommends COVID-19 vaccines types have storage temperature needs: 2 °C to 8 °C, -20 °C, -70 °C +/-10 °C (WHO, 2019).

Even if a number of new vaccines have been rolled out across the developing world; cold chain systems are struggling to support national immunization programs by reduced potency of vaccines. This risks due to poor temperature control, nonfunctional cold chain equipment, low availability of immunization supplies (inadequate storage capacity, disrupted service delivery, vaccine stock outs, etc.) and inefficient use of limited financial and human resources (e.g.

through losses from vaccine wastage). Therefore, improving cold chain systems can expand effective immunization coverage and further decrease the number of deaths caused by vaccine preventable diseases. (Global Action Plan, 2011-2020).

So, vaccines require more complex handling and storage requirements due to increased temperature sensitivity and complicated immunization schedules and to achieve the success of Expanded Program on Immunization (EPI) is therefore highly sensitive to the cold chain status and hence its management should not be taken lightly (Yakum *et al.*, 2015).

Despite the many advances in immunization in Ethiopia there are numerous challenges in management of cold chain of vaccines. These include insufficient cold chain capacity, lack of up-to-date technology or ‘optimal’ equipment and inadequate temperature monitoring and maintenance systems. These challenges will lead to vaccines become compromised and less potent. (Ashvin *et al.*, 2016).

Cold chain systems are struggling to support national immunization programs because of challenges in major components of vaccine supply chain which related to storage system, distribution system, storage capacity and management procedures (Global Action Plan, 2011-2020 and Firomsa B., 2018). Hence, this study was conducted to assess Challenges of COVID-19 vaccines cold chain management practices and vaccine utilization in selected government health facilities under Addis Ababa Health Bureau.

## **1.2. Statement of the problem**

Inadequate monitoring of temperature, poor compliance to cold chain procedures, use of outdated cold chain equipment, improper management and poor understanding to effect of vaccine freezing are affects cold chain management practice negatively in many countries. (Joao *et al.*, 2007)

Main COVID-19 vaccine cold chain management challenges are Insufficient cold-chain capacity, outdated cold-chain equipment, Inadequate maintenance and monitoring, Lack of relevant skills and adequate training, Limited or unreliable energy access, Lack of financing, unable to access electric power, inadequate infrastructures in many South East Asian, south Asian and African countries (Xinfang Wang *et al.*, 2020).

A study conducted in Lagos, Nigeria showed that because of improper vaccine storage  $\frac{3}{4}$  of the vaccines was sub- potent were with outbreaks of vaccine preventable diseases in several developing countries and the situation continuous not to improve over the three-year study period(Dairo, 2016).

A study conducted in Sudan showed that challenges of cold chain management was a lack of infrastructure for the storage and transportation of vaccines, a health workforce shortage, inequity in the distribution of health facilities, and vaccination hesitancy. (Alanood E *et al.*, 2021).

Major challenge in developing countries was access to vaccines it caused by the lack of integrated and appropriate cold-chains, which result in distribution failure points, leading to vaccine wastage, missed opportunity for vaccination, and ineffective immunization program(Xinfang Wang *et al.*, 2020)

Not keeping vaccines in a safe temperature range in the cold chain is one challenge. For instance, in Cameroon and Ethiopia studies a reading was out of the recommended range in 25 percent (Richard *et al.*, 2014).

The main challenge is cold chain monitoring in many developing countries such as Tanzania because of poor transportation infrastructure, unreliable electric supply shortage of trained personnel and proper equipment to store temperature sensitive commodities (WHO, 2006).

After reviewing literature almost all study did not focus on Covid-19 vaccine. Therefore, this study was providing information to improve COVID-19 cold chain management practice.

### **1.3. Objective of the study**

#### **1.3.1 General objective**

The general objective of the study was to assess the challenges in COVID-19 vaccines cold chain management practices and utilization in selected government health facilities in Addis Ababa

### 1.3.2. Specific objectives

- To assess the COVID-19 vaccine cold chain management practices of selected government health facilities under Addis Ababa Health Bureau
- To identify the major challenge affecting COVID-19 vaccine cold chain management practices in selected government health facilities under Addis Ababa Health Bureau
- To assess COVID-19 vaccine utilization in selected health facilities under Addis Ababa Health Bureau

### 1.4. Significance of the study

The Results of this study will help to reinforce existing knowledge of cold chain management of vaccines practice, identify gaps that exist in COVID-19 cold chain managements, Utilization of COVID-19 vaccine and recommendation will used for improvement to cold chain management practice. The finding of this study will be used to improve COVID-19 vaccine cold chain management practice and the studies will also provides information on challenges and health facilities can simply work on contributing factors for solution and to give appropriate interventions can be made to improve health facilities practice and provide insight into further research needs in these areas or could serve as base line data for researchers.

### 1.5. Scope of the Study

The scope of the research contains the cold chain management practices; storage capacity, stock management, cold chain equipment and Temperature monitoring/control and challenges related to cold chain management practice and utilization Covid-19 vaccine in health facilities under Addis Ababa.

### 1.6. Operational definition of terms

**Cold Chain:** The system used for storing vaccines in good condition and it consists of a series of links that are designed to keep vaccines within WHO recommended temperature ranges, from the point of manufacture to the point of administration (WHO & UNICEF, 2014)

**Temperature Control:** All vaccines and their diluents are stored and distributed within a cold-chain system that maintains, at all times, the WHO-recommended temperatures range for all types of vaccines (WHO & UNICEF, 2014).

**Storage Capacity:** cold chain which has sufficient and quality cold storage, dry storage and transport storage capacity to accommodate all vaccines, diluents and injection supplies needed for the national immunization program (WHO & UNICEF, 2014).

**Stock Management:** Systems and procedures for managing the stocks of vaccines are effective, in terms of vaccine handling, physical inventory, stock-control systems, adequate stock-level policy, good warehousing practice, and disposal procedures for damaged and expired vaccines (WHO & UNICEF, 2014).

**Cold Chain Equipment:** All equipment used for storing, transporting and monitoring vaccines (WHO & UNICEF, 2014).

### **1.7. Organization of the study**

The study was organized in to five chapters each dealing with different ideas for one common purpose. In chapter one; background of the study, statement of the problem, objective of the study both general and specific objectives, significance of the study, scope of the study, were included. In chapter two, reviews of theoretical, conceptual frame work and empirical literatures were included to support the study. In chapter three; research design and methodology was briefly discussed including the research type, population of the study, sampling method, sample size, data collection instrument, and method of data analysis. In chapter four result and discussion of the study and in chapter five summaries, conclusions and recommendation was included. Questionnaires and other documents used in the study are annexed in appendices.

## CHAPTER TWO

### 2. RELATED LITERATURE REVIEW

*This chapter focused on previous research studies conducted globally, in African countries and in Ethiopia and has Theoretical Review which contain the vaccine cold chain practice which is the effective vaccine management and after that empirical literature and conceptual frame is proceed work by focus on the objective of the study.*

#### 2.1. Theoretical literature review

##### 2.1.1. Cold chain management system

Effective Vaccine Management (EVM), launched by the WHO and UNICEF in 2010, EVM measures a wide spectrum of programmatic activities, including the following storage capacity, stock management, cold chain equipment and Temperature monitoring/control and logistics management information systems (WHO & UNICEF, 2014).

Effective vaccine management play critical roles by prevent vaccine-preventable diseases. But when vaccines exposed to outside the recommended ranges in storage temperatures it leads to reduced potency, creating limited protection and resulting in the revaccination of patients and thousands of dollars in wasted vaccine. Therefore, Proper storage and handling is mandatory (CDC, 2019).

Some of COVID-19 vaccines needs storage at ultra-low temperature (ULT) to maintain potency, especially the messenger ribonucleic acid (mRNA) vaccine types WHO listed the Covid-19 mRNA vaccine for emergency use, this poses additional challenges to cold chain storage and transport, especially in remote areas, away from major transport links and refrigeration facilities, and places with unstable power supply (WHO, 2021a)

##### 2.1.2. Storage and handling of vaccine

Vaccines types require different storage, temperatures and the entire vaccination process from the original manufacturing to final vaccine administration involve various refrigerated transportation and storage systems (ASHRAE, 2014).

CDC Vaccine Storage and Handling Toolkit explain temperature classes: medium temperature refrigeration (2°C to 8°C), low temperature refrigeration (-50°C to -15°C) and ultra-low

temperature refrigeration (-90°C and -60°C). Covid-19 vaccine require medium temperature refrigeration Janssen COVID-19, inactivated vaccines, low temperature refrigeration (Moderna COVID-19), ultra-low temperature refrigeration (Pfizer-BioNTech COVID-19, Ervebo).(CDC,2021a).

### **2.1.3. Cold chain equipment**

To ensure a safe cold chain and potent vaccines cold chain depends on the many element one element is appropriate transport and storage equipment and accurate vaccine inventory management.(CDC, 2018).

WHO recommend; WHO standard refrigerators for storing vaccines but most domestic refrigerators which are not fan- forced and have poor temperature recovery after the door has been opened. Standard vaccines refrigerator recorded minimum and maximum temperature and give alarm if the temperature goes out of specifications (WHO, 2016).

Infrastructures of cold chain consist of large quantities of dry ice are used for transportation of vaccine. (ASHRAE, 2014).

### **2.1.4. Stock management**

According to vaccine storage and handling tool kit 2018, vaccines are expensive, so it's important to ensure stored correctly and to account for every dose received and used by facility, whether administered, wasted, compromised, expired, or transferred. To avail the vaccines as needed there should be keeping accurate records to assist in ordering and rotating stock on a regular basis. (CDC, 2018).

To had a proper stock keeping tools record the information of vaccine presentation (vial size), quantity received in doses, vaccine manufacturer, manufacturing batch or lot number, expiry date of each vaccine batch, VVM status where applicable, location in the store is mandatory. Received vaccines must be checked immediately for exposure to heat or freezing, if it is damage and see expiry date. After that it must, transfer to the refrigerator immediately and minimize the time that the refrigerator door is open. If there is any concerns about vaccine delivery, isolate the vaccines in the vaccine refrigerator and contact the supplier. Stock must be rotated with the first expired, first out rule (WHO and UNICEF, 2014).

### **2.1.5. Storage capacity**

To secure vaccine effectiveness vaccine has been stored correctly. It should be stored in the original packaging, retaining batch numbers and expiry dates. Prolonged exposure to ultraviolet light will cause loss of potency. Within the refrigerator, sufficient space around the vaccine packages should be left for air to circulate. Vaccines should be kept away from the side and back walls of the refrigerator; otherwise, the vaccines may freeze rendering them inactive and unusable. Vaccines must be stored properly from the time they are manufactured until they are administered. Assuring vaccine quality and maintaining the cold chain is a shared responsibility among manufacturers, distributors, public health staff, and health-care providers (CDC, 2018).

## **2.2. Empirical literature review**

### **2.2.1. Cold chain management practice**

Concern is placed on major cold chain management practices; the storage, handling, transportation and distribution of vaccines because vaccines are temperature sensitive. Active and passive cooling equipment and monitoring devices are important tasks in vaccine cold chain.(WHO 2018).

Accidental freezing still occurs in 33% of storage facilities in wealthy countries and 37% of facilities in lower income countries and cold chain equipment is failing and underperforming in 20 and 50%(Immunization supply chains 2017).

Developing countries have less mature cold chain systems than do high income economies, with various degrees of maturity within them. Existing cold chain capacity within developing countries is largely for the vaccine which can put in temperature range 2 to 8 °C. However, ultra cold chain freezer capacity -70°C e.g. Pfizer-BioNTech vaccine requires ultra-cold chain capacity for storage longer than about six weeks (CDC,2021b) and traditional freezer capacity at -20°C e.g. Moderna vaccines requires traditional freezer capacity for storage longer than about one month (CDC,2021c)

The study done in Nigeria reported that more than six-tenth of health care workers had poor practice with regards to cold chain monitoring and storage (Jennifer O *et al.* 2017).

The study reported in Cameron found that the cold chain standard is compromised and only and only 2 percent of facilities were equipped with devices that are approved for vaccine storage by the WHO PQS system (Divine, N. *et al.*, 2019).

With regard to storage capacity gaps, 45% of health districts had capacity gaps in 2017, a percentage that is projected to reach 75% by 2021. Unlike districts, almost all facilities had cold chain capacity gaps in 2017 and this percentage is expected to reach 99% by 2021 if no intervention is implemented (Divine, N. *et al.*, 2019). There was no statistically significant difference regarding vaccine storage between urban and rural sites. Lack of technicians for refrigerator maintenance and budgetary constraints were reported by (61.2%) and (89.6%) of the institutions respectively. These problems were more encountered in the urban centers compared to the rural ones (Rogie, B., Berhane, Y., 2012).

According to the study conducted at EPI service provider facilities of Addis Ababa, there have been challenges in major components of vaccine supply chain which are related to storage system, distribution system and technical capacity and management procedures (Firomsa B., 2018).

### **2.2.2. Challenges in COVID 19 vaccine cold chain management practices**

**A. Insufficient cold chain capacity:** there are serious consequences occur when there is inadequate capacity, such as new vaccine's availability can be delayed or overwhelm existing capacity leading to exposed vaccines and stock outs. (Zaffran M *et al*, 2013). According to the study conducted in private health facilities of Addis Ababa, challenges have been emerge in major components of vaccine supply chain practice which are related to storage system, distribution system and technical capacity and management procedures (Firomsa B., 2018).

Many of the typical supply chain challenges are exacerbated including improper storage of vaccines, and unsatisfactory knowledge in cold chain management at health facility levels. (Muluken A , MesganawF, 2013). Research done for the status of surveillance and routine immunization performances in Amhara region, there had been vaccine stock out in the 3 months before assessment in 28/82 (34%) of the sites (Lakew GA *et al.*, 2017).

**B. Unsafe technology and slow adoption of better equipment:** Because of the performance of cold chains has been hinder by large quantities of outdated equipment, which fails to provide the protective benefit of more recent designs. Breakdowns in equipment at any level pose an even higher risk to vaccines, this can disrupt stock and vaccine management principles, resulting in higher levels of damaged or expired vaccine stock.(Zaffran M *et al*, 2013). Temperature damage

to vaccines is a known problem in many countries, and is often driven by failures in equipment. This poses major risks to national programs in Ethiopia alone, a 1 percent increase in vaccine wastage due to poor temperature control and use nonfunctional cold chain equipment would result in losses of over US\$8 million of vaccines per annum (D.M.matthias *et al.*, 2007, J.Lloyd *et al.*, 2015, S.Techathawat *et al.*, 2007, M.V.Murhekar *et al.*, 2013 and G. Chukwuma *et al.*, 2013).

Assessments done in the North West region of Cameroon, 53 out of 65 health facilities (81.5%) had at least one functional vaccine refrigerator (Yakum *et al.*, 2015). Study conducted in private health facilities in Addis Ababa 24(48%) facilities states that their factor affecting cold chain management is related to the standard of cold chain fridges currently used by facilities. The other is mentioned by 4(8%) facilities were shortage of vaccines supply from respective suppliers (sub city health offices) and EPI trained staff turnover (Alemtsehay B., 2020).

Vaccine storage in the refrigerator was not proper in 47/64 (73.4%) health centers. Majority of the health centers had neither trained personnel nor budget for maintenance of the cold chain (Berhane *et al.*, 2000). Problems with vaccine storage are common and mainly relate to inadequate monitoring of cold storage units or use of freezer units in inappropriate, small refrigerator/freezer units. One of the major problems facing Nigeria's vaccine supply chain is the lack of adequate vaccine storage facilities (Ekundayo *et al.*, 2016). There were vaccines cold chain management practice challenges specially lack of vaccine standard fridges to maintain the recommended temperature range, temperature monitoring, vaccine storage and handling practice and to maintain vaccine potency practice in private health facilities providing EPI service in Addis Ababa (Alemthehay, 2020). While a number of new vaccines have been rolled out across the developing world (with more vaccines in the pipeline), cold chain systems are struggling to efficiently support national immunization programs in availability of safe and potent vaccines. (Ashvinet *et al.*, 2016).

**C. Inadequate temperature control and maintenance systems:** Evidence from cold chain inventories show that in Cameroon, Tanzania, Ethiopia and Uganda are struggling to maintain required storage temperatures, with 17–33% of cold chain equipment (CCE) across four countries found to be inactive at time of assessment. Temperature monitoring studies (TMS) have found that active CCE are often not functioning properly, temperature

control problems. Malfunctions are common at the facility level, where CHAI and partner-supported TMS have found that between 10 percent and 46 percent (mean, 29 percent) of CCE are exposing vaccines to freeze risk (Ashvin, 2016). Assessments done in 440 storage units found in developed and developing countries, the percent of storage units where vaccines were exposed to temperatures below recommended ranges were 33.3% in wealthier countries and 37.1% in lower income countries (Hanson *et al.*, 2017).

A study done in New South Wales by WHO in 2011 used data loggers to measure the temperature of 53 vaccine refrigerators in pharmacies and found that only 19 percent of the refrigerators studied had temperatures that fell within the acceptable range, while 23 percent of the refrigerators had temperatures that fell to less than 0°C and 29 percent had temperatures higher than 8°C (WHO and PATH, 2011).

The assessment done in Thailand showed that vaccines were stored at a temperature lower than 0°C on 32 out of 43 facilities, the major problems reported were that the refrigerator temperature was not in the range of 2°C to 8°C in 22% of the health facilities. Also, vaccine freezing was detected at the provincial level (50%), the district level (29%), and health centers (28%) (WHO and PATH, 2011).

In addition, vaccines have been exposed to freezing in 15.79% of the facilities at Benin (Agueh *et al.*, 2016), and in North West region of Cameroon facility 43.8% cold chain managers in they did not know the recommended vaccine temperature storage range. (Yakum *et al.*, 2015).

**D. knowledge gap of health worker:** The study reported in east Gojam zone of Amhara region indicated that there was a knowledge gap of health workers who are working on cold chain management. The findings of this study indicate that there are important knowledge gaps for health workers in managing the cold chain management. To improve knowledge and practice on cold chain management through improved supervision and training at a different level of health care system although only 21(35%) of storekeepers knew the correct placing of the thermometer. (Hewan *et al.*, 2019).

**E. Irregularities in electric power supply:** The cold chain system is assumed to be at greatest risk, particularly in tropical countries where a power supply is unreliable and facilities for its maintenance are not well developed. In these areas, it is common to observe 30–50% of the

refrigerators and freezers being out of order. In Ethiopia, there is a real problem of vaccines losing their potency during storage at these centers even if they were potent on arrival. The major challenge of this type of power supply was an irregularity in the power supply. Availability of necessary spare parts and conducting cold room maintenance were very low (Hewanet *et al.*, 2019).

In tropical countries where a power supply is unreliable cold chain system had a greatest risk particularly and facilities for its maintenance are not well developed. (Ogboghdo *et al.*, 2017, Dairo2016).

### **2.2.3. COVID-19 Vaccine Utilization**

The development and widespread use of an effective SARS-CoV-2 vaccine could prevent morbidity and mortality associated with COVID-19 (Brody, 2021). Vaccine safety is critical for the successful implementation of any vaccination program, especially during the pandemic (Grace,2021). COVID-19 vaccine is rolled out and available in some countries. However, strategies need to be put in place to prevent COVID-19 vaccine hesitancy especially in Africa (Aanuoluwapo, 2021). Due to the short shelf-life; several countries have faced challenges with utilizing all available doses of vaccines before the expiry date. It is of utmost importance that countries ensure the utilization of all available vaccine doses. Bulgaria had only administered 43 percent of doses that had been distributed (WHO, 2021d).

Due to the short shelf life, several countries have faced challenges with utilizing all available doses of COVID-19 vaccines before the expiry date (WHO, 2021d).

The expected health benefits from a vaccine development project depend not only on the number of potential recipients of the vaccine (the target population), but also on the proportion of the target population that will actually receive it. However, predicting future utilization rates of vaccine candidates is difficult, even for a relatively homogeneous population, because vaccine utilization depends on many interrelated and complex factors. These factors include: including availability, cost, the health system capacity to deliver vaccine, statutory interventions, the target population, and provider and recipient acceptance (Institute of Medicine (US), 1986)

### **2.3. Literature gap**

After COVID-19 vaccine is manufactured many people are vaccinated. Preventive vaccination takes place before a disease emerges and aim at preventing a disease outbreak. Although

vaccination is a medical intervention, successful vaccination campaigns are impossible without good cold chain management practice. There are a number of empirical literature involving cold chain capacity, storage temperature, stock management and cold chain equipment system both globally and different perspective. But due to time and resource constraints, the study was limited only to public health facilities under Addis Ababa health office.

#### 2.4. Conceptual Frame Work of Challenges in Covid-19 vaccine Cold Chain Management Practice

COVID-19 vaccine needs its specific storage requirements. Components of effective vaccine management practice which are cold chain practice are cold chain equipment, storage capacity, stock management and vaccine temperature monitoring. The researcher was assessed vaccine management practice, basically the key in above cold chain practice. Challenges in cold chain management practice in insufficient cold chain capacity, lack of vaccine standard fridge and slow adoption of better equipment, inadequate temperature monitoring and maintenance system, knowledge gap of health workers, Irregularities in electric power supply and utilization of Covid-19 vaccine.

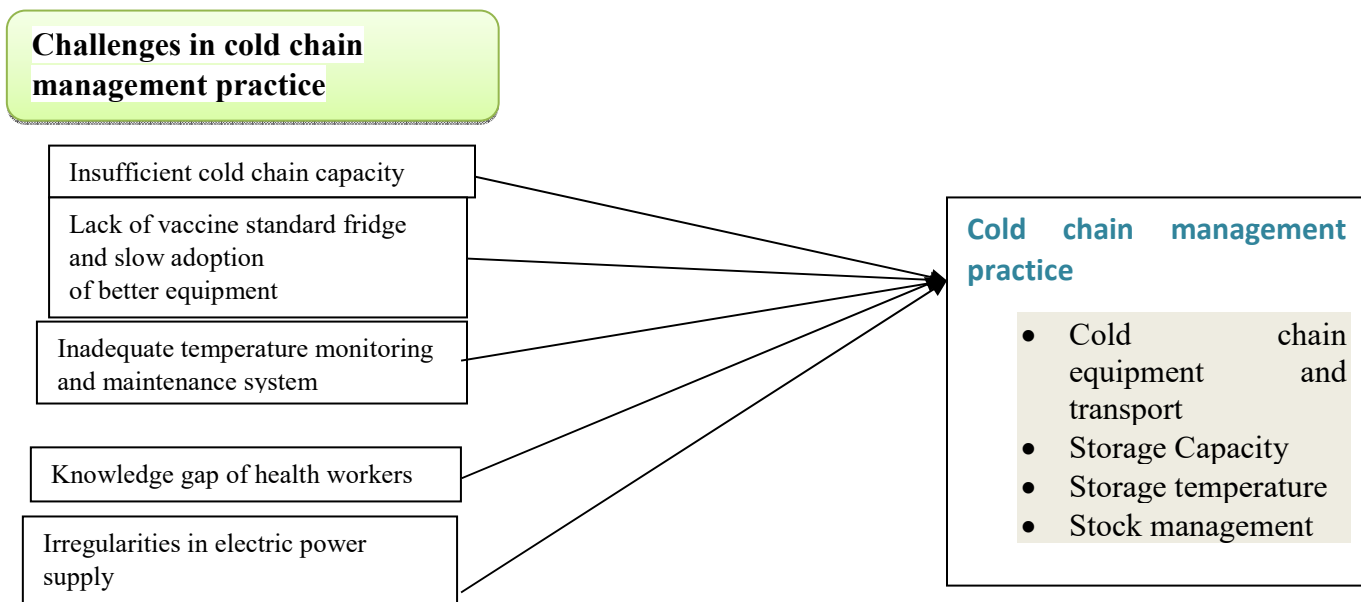


Figure 1: Conceptual frame work adopted from Effective Vaccine Management Assessment Tool (VMAT module 2, WHO 2005),WHO Vaccine tool kit CDC 2019, Xinfang,2021)

## CHAPTER THREE

### 3. METHODOLOGY OF THE STUDY

*This chapter has presented the research methodology used to guide the study. The research design, instruments for data collection procedure, validity and reliability of the research instruments, sampling procedure, the method for analyzing the data collected is described.*

#### 3.1. Description of Study Area

The study was conducted in governmental health facilities at Addis Ababa, Ethiopia. Addis Ababa is the capital city of Ethiopia, and is most densely populated cities in the country, with an estimated at 5,005,524(World review, 2021).

Administratively, Addis Ababa city is divided in to 11 sub-cities administration. According to the 2013 E.C. health and related indicators published by FDRE Ministry of Health, there are 100 health centers in Addis Ababa and 7 Hospitals as presented in the following table.

**Table 1:Name of health facilities**

Name of Sub-city /Hospital	Number of Health center
Lideta sub-city	8
Arada sub-city	10
Akaki sub-city	9
Bole sub-city	7
Nifas silk sub-city	9
Addis ketema sub-city	13
Kirkos sub-city	8
Gulele sub-city	10
Yeka sub-city	10
Lemikura sub-city	9
Hospitals in AARHB (Yekatit 12 &AbebechGobena Hospital, Gandhi MH, Zewditu MH, Minilik II R.H ,RasDesta DMH, Tirunesh Beijing Hospital,	7

#### 3.2. Research design and Study period

Research design was facility based cross sectional, explanatory and descriptive research designed at employed for the study at government health facilities providing COVID-19 EPI service in Addis Ababa City Administration. The study was conducted from February to March 2022GC.

### 3.3. Research approach

Both quantitative and qualitative research approaches was fitted. Qualitative items are an add-on to a quantitative survey by including a few open-ended qualitative questions.

### 3.4. Population

#### 3.4.1. Source population

The source population for this study was health facilities and health professional in the governmental health facilities under Addis Ababa city administration.

#### 3.4.2. Study population

The study population was EPI focal person who work in governmental health facilities under Addis Ababa health office.

### 3.5. Sample size determination

To generate representative the sample health facilities were calculated using the formula and statistical assumptions presented below which is a single population proportion formula for cross sectional study

Where:

n = Sample size

$Z_c^2$  = Confidence level, 1.96 (95% confidence level)

FPC = Finite population correction factor

P = proportion = 50%

d = Margin of error (MOE), 5%

$$n = Z_c^2 \times P \times (1-P) / d^2 \times FPC$$

Using the above assumptions it was calculated that a total sample size becomes 47 facilities for the study by applying  $n = N * (n / (N + n))$  where N= 42health facilities.

A total 107 health facilities -----sampled 42 health facilities

100 health centers.....39 health centers

From 42 health facilities (39 health centers and 3 hospitals) include but the number of health center increased from 39 to 44 in order to meet the proportionate sampling for each sub-city and four health centers will be selected from sub-city. The sample size (44 Health Centers+ 3

Hospitals) was allocated proportionally to 11 sub-cities. Therefore; from each of the 47 health facilities one EPI focal person was contacted (the response rate of the questionnaire survey was 100%)

### **3.6. Sampling Procedures**

There are 100 governmental health centers and seven hospitals in Addis Ababa City Administration, which are under Addis Ababa administration, will be included. The study population will be categorized under two strata namely, governmental health center and hospitals.

The sample size for qualitative study was determined by the saturation of information concerning emerging themes. For qualitative data, key informants were purposely selected that are expert from health facilities who are good knowledge involved in COVID -19 vaccine cold chain management (EPI focal person) was interviewed until data saturation. (which finally accounts total of 7 of interview).

### **3.8. Instruments and data Collection Procedures**

Data was collected through self-administered questionnaire and open ended surveys. Data collectors were briefed on how to collect data for one day. That was to let the data collectors understand each question in the questionnaire and hence guide them to provide direction during providing data collection tool to the vaccine focal person. Supervisors were giving duties of checking for completeness and facilitating the field work. The investigator was coordinating the daily activities of data collectors and supervisors. Structured questionnaire prepared for this study as shown in annex 1, which consists of three main categories namely socio-demographic variables, COVID-19 cold chain management practices, COVID-19 challenges and utilization in cold chain management practices. (Five point Likert's Scale questionnaire)

Open ended surveys were used to collect information regarding questions related to cold chain management practice, the interview was used in challenges and utilization in COVID -19 cold chain management practice question until data saturation. The interview lasted on average 25 minutes. The in-depth interview was carried out face to face in health facilities (EPI focal person) by investigator. The response from in depth interview was audio recorded and transcribed verbatim on Microsoft word. The transcribed interview was done via coding and data

were categorized into themes. After those contents was summarized and analyzed based on thematic analysis. Data analysis was carried out soon after the first six interviews were conducted: such analysis will guide further data collection and data saturation of themes. The media of interview was in Amharic and selected participants quotes were transcribed from Amharic to English. Using purposive sampling, an expert who has a good knowledge (EPI focal persons) on COVID -19 vaccine cold chain management practice was selected.

### 3.9. Validity and Reliability

Reliability of data was confirmed using SPSS tool, after all the data had been enter in to the software, reliability analysis was done. Testing reliability and validity is described on the reliability of measuring tools employed in this research. The validity of tool was checked by a pilot test; was run to make sure it was understandable and acceptable to the intended audience. Pilot test was performed in two health centers at conducting pilot study.i.e.,5%.

Questionnaire data was checked by investigator for the consistency and completeness. After the responses are transcribed, a summary of the major findings of the in-depth interview were sent for participants to comments and ideas that are not include during the interview were incorporated.

Most common technique used in the literature to assess the scale’s reliability and stability is use of Chronbach Alpha Statistics, Reliability is considered to be good if the reliability analysis test value is greater or equal to 0.7.Accordingly, the study was reliable based on the analysis obtained with a Cronbach’s Alpha result of 0.719 which indicates very well reliability to capture the construct.

**Table2: Reliability statistics**

<b>Cronbach's Alpha</b>	<b>N of Items</b>
<b>.719</b>	<b>45</b>

### 3.10. Data Analysis

Data entry and cleaning was done by principal investigator. The data obtained from health center was analyses according to objective of the study. To ensure completeness and consistency, data editing and coding was carried out by principal investigator before being entered into the analyzing software. Finally, the data obtained through data collection instrument was analyzed

quantitatively using SPSS version 20 and data was summarized with descriptive statistics using percentage, frequency, mean and standard deviation. Further to this Logistics regression analysis was conducted to see relationship between variables. Regression analysis is a statistical method to investigate relationships between more than one independent variable and only one dependent variable. Qualitative data was analysed by using thematic analysis. The data was followed this step to analyses; familiarization, coding, generating themes, reviewing themes, defining and naming themes, and writing up.

### 3.11. Descriptive analysis

The respondents were required to indicate on a Likert scale of 1-5 was used where: 1= Strongly Disagree, 2= Disagree, 3= Neutral, 4= Agree and 5= Strongly Agree.

**Table 3: Interpretation Mean Scale**

Scale	Interpretation for practice	Interpretation for challenges
1.0 – 2.6	low practice/	Not influential
2.61– 3.40	slightly practice	Slightly influential
3.41 – 5.00	Well practiced	Influential

Source: Alexander B. (2009) and Alfarra (2009)

### 3.12. Ethical Considerations

Ethical approval and clearance was obtained from Ethical Review committee of school of pharmacy, Addis Ababa University and Addis Ababa public health research emergency management directorate. Supportive letter was obtained from department of pharmaceutical and social pharmacy. Permission to conduct the study was also request from Addis Ababa health Bureau. Informed consent was asked to the study participant to confirm willingness for participation after explaining the objective of the study. The respondents have also the right to refuse or terminate at any point of time. The information provided by each respondent was kept confidential through anonymous recording and coding of questionnaire.

### 3.13. Dissemination plan of the results

Results of the study will be disseminated to Addis Ababa Public Health Research Emergency Management Directorate and Addis Ababa University, School of Pharmacy.

## CHAPTER FOUR

### 4. RESULT, DISCUSSION AND INTERPRETATION

This chapter deals about finding of self-administer question and interview, provide detailed analysis of data collected from survey based on the objective of the study. A total 24 health facilities providing COVID-19 vaccine were included in the study. The response rate the questionnaire survey was also 96(100%).

#### 4.1. Socio demographic Characteristics of the study population

Table 4.Socio-demographic characteristics of respondents in Addis Ababa, Ethiopia, 2022 N=47

Characteristics n=47		Frequency	Percentage
Gender	Male	23	48.9%
	Female	24	51.1%
Work Experience	1-5	5	10.63%
	6-10	29	61.7%
	>10	13	27.67%
Age groups in year	>25yrs	2	4.26%
	25-32yrs	37	78.72%
	33-39yrs	7	14.9%
	>48yrs	1	2.12%
Education status	BA/BSC	22	46.8%
	Diploma	25	53.2%

Data source: Survey result, 2022

Table 3, indicate gender, work experience, age, education status and type of health facilities Regarding gender 24(51.1%) of participants were female and 23(48.9%) were male and most of participants experience is 6-10 (61.7%).The majority of participants were (78.72%) of participants were in age group of 25-32yrs.Regarding education status 25(46.8%) of participants were degree graduated, 22(53.2%) were diploma graduated. About 44(93.6%) of health facilities contacted were health centers and 3(6.4%) of facilities were hospitals.

#### 4.2. Cold Chain Management Practice of COVID-19 Vaccine

In cold chain management practices cold chain equipment and transport, vaccine storage temperature, stock management and cold chain capacity are include below table.

**Table 5. COVID-19 Vaccine Cold Chain Management Practice N=47**

<b>A</b>	<b>Cold chain equipment and transport</b>	<b>Mean</b>	<b>Std. Dev</b>
1	WHO standard cold chain fridge vaccine storage is available in the health facility	3.4	1.27
2	Temperature monitoring system during transportation(Thermometer with vaccine carrier)	2.7	1.66
3	Temperature reading remain between 2-8 c during transportation	3.5	1.73
4	There is cold boxes, vaccine carriers and refrigerator for vaccine storage are available in the health facility	4.5	0.585
5	All refrigerators have a working temperature monitoring device stored with the vaccine in the health facility	4.4	1.24
	<b>Grand mean of Cold chain equipment and transport</b>	<b>3.7</b>	
<b>B</b>	<b>Cold chain capacity</b>	<b>Mean</b>	<b>Std. Dev</b>
1	The facility has refrigerators to meet peak demand is available in the facility	2.89	1.68
2	Sufficient cold boxes, vaccine carriers for vaccine storage are available in the health facility	4.0	1.39
3	There is alternative storage (e.g., refrigerator, Cold box)	3.12	1.7
	<b>Grand mean of Cold chain capacity</b>	<b>3.3</b>	
<b>C</b>	<b>Vaccine storage temperature</b>	<b>Mean</b>	<b>Std. Dev</b>
1	Vaccines are stored in the correct freezing temperature of the freeze sensitive vaccines $-(50-15)^{\circ}\text{C}$ on the schedule at the health facility.eg Pizer	1.34	0.47
2	Refrigerated vaccines are presented in temperature between 2-8 $^{\circ}\text{C}$ .	4.85	0.35
3	The facilities where daily temperature monitoring chart recorded daily.	3.9	0.359
	<b>Grand mean of Vaccine storage temperature</b>	<b>3.39</b>	
<b>D</b>	<b>Stock Management</b>	<b>Mean</b>	<b>Std. Dev</b>
1	All receipts and dispatches are recorded and balances are updated stock record log book	<b>4.2</b>	0.5
2	Vaccine delivery from respective supplier done within the regular schedule	3	1.33
3	The vaccine management practice of health facility follows FEFO principle	4.5	0.43
4	Expired vaccines are not presented in the refrigerator in the health facility	3.3	1.85
5	The vaccine storage area protected from direct sun light in the health facility	4.6	0.81
6	Vaccine Vial Monitors status of vaccine is recorded for COVID -19 vaccine in the health facility	1.3	0.6
	<b>Grand mean of Stock Management</b>	<b>3.4</b>	

#### **4.2.1. Cold chain equipment and transport practice**

The cold chain practice of COVID -19 in terms of cold chain equipment and transport accounts a grand mean value of 3.7, this indicates cold chain equipment and transport is being well practiced as per the range suggested by Alfara (2009).

According to world health organization recommendation domestic refrigerator is not recommended for vaccines.

(WHO&UNICEF, 2014) This study revealed that only 27(57%) health facilities strongly agree and agree on WHO standard cold chain fridge vaccine storage is available in the health facility. This finding is lower than the study done in private facilities in Addis Ababa 44(88%), but higher than the finding from Cameroon where only (18%) of facilities were using domestic fridge.(Firomsa B. 2018,Divine *et al*,2019)

Regarding the icepacks, 42.5% (n=20) of the health facilities had no sufficient icepack and icepack freezing capacity. Similar assessments were done in Nepal shown that 80% at service delivery point level, the available icepack freezers have sufficient capacity to meet the maximum daily demand for icepacks (M.V.Murhekar *et al*, 2013). Regarding the cold box availability, 83.3% of the facilities had functional cold box and it was comparable with that of the assessment done in central Ethiopia 86.6% (Rogie, *et al*. 2013).

#### **4.2.2. Cold chain capacity practice**

The COVID -19 cold chain management practice in terms of cold chain capacity accounts a grand mean value of 3.3, indicating cold chain capacity is being slightly practiced.

According to CDC vaccines must be stored properly from the time they are manufactured until they are administered. (CDC ,2021a). Assuring vaccine quality and maintaining the cold chain is a shared responsibility among manufacturers, distributors, public health staff, and health-care providers. This study is supported with study conducted in Nigeria to storage capacity gaps, 45 percent of health districts had capacity gaps in 2017, a percentage that is projected to reach 75percent by 2021 (Divine, N.*et al.*, 2019).Regarding the vaccine refrigerator, 27 (45%) facilities had not sufficient refrigerator for vaccine storage and in 23(38.3%) of the facilities one or more refrigerators were nonfunctional.

#### **4.2.3. Vaccine storage temperature practice**

The COVID -19 cold chain practice in terms of vaccine storage temperature accounts Grand mean value of 3.39. This indicates vaccine storage temperature is being slightly practice. Cold

chain practice is essential indicator for success of EPI service. It is the only way to prove that vaccines have kept at right temperature in storage, transport and use. Temperatures must be regularly measured and recorded in order to ensure storage of all vaccines at the correct temperature conditions, and ensure the correct operation of your cold chain equipment (MOH New Zealand 2017).

Regarding daily temperature monitoring activity 33(70.2%) of facilities monitored the cold chain in twice daily bases using temperature monitoring. Similar assessments done in North West region of Cameroon revealed that 49% of the facilities didn't have complete set of twice temperature monitoring records. (Yakum *et al.* 2015) Assessments done at north shoazone, Amahara region 49(81.7%) of facilities monitored the cold chain in twice daily bases using temperature monitoring. The study revealed that facilities where daily temperature monitoring chart recorded daily is good practice which is similar study in Addis Ababa which was 39 (78%) (Alemthehay, 2020)and also higher than similar study conducted in Nekemte (Fekadu *et al*2018) which was 44%.The cold chain guideline recommends the potential COVID-19 vaccines types have varying storage temperature requirements: 2 °C to 8 °C,-20 °C,-70 °C +/-10 °C.

Regarding temperature range 40(85.1%) of facilities had a temperature reading within the normal range of between 2°C and 8°C but in 16 (26.7%) facilities the refrigerator temperature readings were outside the recommended range. The study conducted in three districts of Oromiya, SNNP and Amhara regions of Ethiopia, the thermometer reading was found to be out of the recommended range in 27.3(6%) (Roggie*et al.* 2017)

#### **4.2.4. Stock Management practice**

The COVID -19 cold chain practice in terms of vaccine stock management accounts Grand mean value of 3.4. This indicates vaccine stock management is being slightly practice. In this assessment the variables related to systems and procedures for managing the stocks are effective in terms of vaccine preparing vaccine requisition, stock control system, adequate stock level policy and good storage practice were assessed. Assessments done in Nepal had shown that 24 out of 47 (51%) of stores all vaccine arrivals and vaccine dispatches recorded and stock balances updated within one working day of the transaction, 35 out of 47 (74%) stores reported regular use of vouchers, vaccine is issued according to the 'First- Expiry-First-Out' (FEFO) principle in 27 out of 47 (57%) assessed stores, the storekeeper can make exceptions to the FEFO rule (e.g. because of VVM status) in all (100%) stores, 29 out of 47(62%) stores carried out a physical

inventory of vaccine, diluents and dropper stocks at least equal to the planned supply frequency at lower levels. 16 out of 47 (34%) stores had stock count and records match exactly (M.V. Murhekar *et al*,2013) and (WHO&UNICEF 2014). Comparing the current study with the assessment in Nepal, the current study was better in applying FEFO rule, preparing vaccine requisition to the supplying facility. There was better implementation in vaccine requisition form because of the principle that without report no product, the higher supplying facility didn't issue without the vaccine requisition form. In using receiving and issuing voucher the result had no significant difference. Regarding VVM status is not applied here because COVID -19 vaccines does not have VVM.

Similarly, interview is made to triangulate the finding and it was formulating that EPI Focal persons describe about COVID-19 vaccine cold chain management practice below. The first question was **“How COVID 19 vaccines cold chain management practice in your health facilities?”**

Almost all *EPI focal persons* **Excerpt:** (participant1, 2,5&6)described about their practice regarding to COVID-19 vaccine cold chain management: most of the facility explain the practice in the following way. First received vaccines checked immediately for exposure to heat or freezing, if it is damage and see expiry date. After that it must, transfer to the refrigerator immediately and minimize the time that the refrigerator door is open. If there are any concerns about vaccine delivery, isolate the vaccines in the vaccine refrigerator and contact the supplier. Stock must be rotated with the first expired, first out rule based on their expire date. but **Excerpt:**(participant 3,4 &7) they experience some drawbacks like the received vaccines may store in store room (domestic refrigerator) rather than EPI room refrigerator (WHO standard refrigerator)**Excerpt:**(participant 1,2) because of low capacity for storage vaccines expose to freeze or temperature.

Conclusively, the descriptive analysis result and interview results are the same both results indicate as EPI focal persons described about practice of COVID-19 vaccine through interview.

### 4.3. Challenge in Covid-19 Vaccine Cold Chain Management Practice

In this sub topic there are challenges in Covid-19 vaccine cold chain management practice which are insufficient cold chain capacity, lack of latest technology or standard vaccine fridge, inadequate temperature monitoring and maintenance system, irregularities in electric power supply.

The respondents were required to indicate on a Likert scale of 1-5 where: 1= Strongly Disagree, 2= Disagree, 3= Neutral, 4= Agree and 5= Strongly Agree.

**Table 6. Challenge in Covid-19 Vaccine Cold Chain Management Practice N=47**

<b>A</b>	<b>Insufficient cold chain capacity</b>	Mean	Standard deviation	
1	Insufficient cold chain capacity negatively affects the availability Cold chain equipment practices of the health facility	3.61	0.87	
2	Insufficient cold chain capacity negatively affects storage and transport temperature monitoring practices of the health facility	3.61	1.35	
3	Insufficient cold chain capacity negatively affects stock management practices of the health facility	3.1	1.4	
	<b>Grand mean of Insufficient cold chain capacity</b>	<b>3.39</b>		
<b>B</b>	<b>Lack of latest technology or standard vaccine fridge</b>			
1	Lack of latest technology or cold chain equipment negatively affects the storage temperature practices of health facility	3.72	1.24	
2	Lack of latest technology or cold chain equipment affects Cold chain capacity practices of health facility	2.53	1.47	
3	Lack of latest technology or cold chain equipment affects the stock management practices of the health facility	2.55	1.45	
	<b>Grand mean of Lack of latest technology or cold chain equipment</b>	<b>2.94</b>		
<b>C</b>	<b>Inadequate temperature monitoring and maintenance system</b>			
1	Inadequate temperature monitoring and maintenance system negatively affects availability cold chain equipment practices of the health facility	2.4	1.17	
2	Inadequate temperature monitoring and maintenance system negatively affects storage and transport monitoring practices of the health facility	2.5	1.28	
3	Inadequate temperature monitoring and maintenance system negatively affects cold chain capacity practices of the health facility	2.8	1.24	

4	Inadequate temperature monitoring and maintenance system negatively affects stock management practices of the health facility	2.6	1.29
	<b>Grand mean of Inadequate temperature monitoring and maintenance system</b>	<b>2.6</b>	
<b>D</b>	<b>Knowledge gap of health workers</b>		
1	Knowledge gap of health workers negatively affects availability Cold chain equipment practices of the health facility	2.61	1.46
2	Knowledge gap of health workers negatively affects Storage and transport temperature monitoring practices of the health facility	2.48	1.54
3	Knowledge gap of health workers negatively affects Cold chain capacity practices of the health facility	3.23	1.43
4	Knowledge gap of health workers negatively affects stock management practices of the health facility	2.51	1.56
	<b>Grand mean of Knowledge gap of health workers</b>	<b>2.7</b>	
<b>E</b>	<b>Irregularities in electric power supply</b>		
1	Irregularities in electric power supply negatively affect Cold chain equipment practices of the health facility	1.42	1.2
2	Irregularities in electric power supply negatively affect cold chain capacity practices of the health facility	1.93	1.27
3	Irregularities in electric power supply negatively affect stock management practices of the health facility	2.1	1.4
4	Irregularities in electric power supply negatively affect storage and transport temperature monitoring practices of the health facility	1.89	1.23
	<b>Grand mean of Irregularities in electric power supply</b>	<b>1.835</b>	

Data source: Survey result, 2022

Based on grand mean value *insufficient cold chain capacity, lack of latest technology or standard vaccine fridge, knowledge gap of health workers and inadequate temperature monitoring and maintenance system* are found to be the four major influential challenges affecting cold chain management practices with grand mean value of 3.39, 2.94, 2.7 and 2.6 respectively. On the other hand, irregularities in electric power supply found to be not influential challenges for the cold chain management practice with grand mean value of 1.835.

Major challenge in developing countries was access to vaccines it caused by the lack of integrated and appropriate cold-chains, which result in distribution failure points, leading to

vaccine wastage, missed opportunity for vaccination, and ineffective immunization program(Xinfang Wang *et al*, 2020)

A study conducted in Sudan showed challenges include a lack of infrastructure for the storage and transportation of vaccines, a health workforce shortage, inequity in the distribution of health facilities, and vaccination hesitancy (Alanood, 2021)

Poor transportation infrastructure, unreliable electric supply shortage of trained personnel and proper equipment to store temperature sensitive commodities are major challenge is cold chain temperature monitoring in many developing countries such as Tanzania. (WHO, 2006)

In most developing countries vaccines have >80% efficacy for the ultra-cold (-70°C and -20°C) storage. (Manoja Kumar, 2021).

On the other hand the majority health care professionals which are cold chain handlers had poor practice and inadequate knowledge to store the vaccines properly. (Zeyneba *et al*,2019)

Similarly, interview is made to triangulate the finding and it was formulating that EPI Focal persons describe about major challenges of COVID-19 vaccine cold chain management practice below. The second question was “What are the major challenges in COVID 19 vaccines cold chain management practice in your health facilities?” According the interview response found to play around the following theme.

- ❖ Insufficient cold chain
- ❖ Outdated cold-chain equipment for ultra-low temperature
- ❖ Wastage increases because of vaccine manage by only shelf life
- ❖ Shortage of vaccines supplies from respective supplies
- ❖ Societies were unwilling to take the vaccine

*A. Insufficient cold chain capacity: According to respondent’s insufficient cold chain capacity is main challenge of COVID-19 cold chain management practice. Participant revealed that there is one refrigerator which was used to store other vaccines and COVID-19 vaccine. That causes the cold chain capacity shortage and it to expose vaccines inadequate temperature. (Participant 1,2,3)*

*Excerpt:* The participant #1 explained that:” we had one refrigerator that was insufficient to put vaccine properly”.

*Excerpt:* Similarly, participant # 2 explained that:” our challenge as a facility is insufficient cold chain capacity”

**B. Outdated cold-chain equipment for ultra-low temperature:** Nearly all participant described for ultra-low temperature refrigeration (Pfizer-BioNTech) COVID-19vaccine there is no standard storage all EPI focal described that vaccine vials to be stored in the refrigerator at 2°C to 8°C (35°F to 46°F) for up to 1 month. (Participant 1-7)

*Excerpt:* The participant # 3 explained that: “We don’t have WHO standard refrigerator (ultra-low temperature refrigeration) so the vaccine manages by shelf life other than expire date”.

**C. Wastage increases because of vaccine manage by only shelf life**

COVID -19 vaccines were managed by shelf life rather than expire date and it increase wastage rate. But many parts of the society were unwilling to take the vaccine. Therefore; the vaccine expired before the society took it. This situation also increased wastage rate.(participant1-7)

**D. Shortage of vaccines supplies from respective supplies:** All Respondent face challenge to give appropriate appointment for vaccination because of in most facilities COVID-19 vaccine delivery was interrupted.

*Excerpt:* Participant #6 explained as follows: “we appoint the person to be vaccinate the second round but because of COVID-19 vaccine delivery was interrupted, we cannot manage” (participant 1, 4, 6)

**E. All participant reflects that COVID-19 vaccine does not have Vaccine Vial Monitoring (VVM) like other vaccine;** especially during campaign or outside facility campaign it was challenging to inspect vaccine if it is expose to temperature or not. (participant1-7)

**Excerpt:** Participant # 5 explained as follows:” COVID-19 vaccine is difficult to inspect by using VVM like other vaccine”. Similarly, Participant #6explained: “We cannot inspect vaccine by VVM, especially during campaign if it is exposed to temperature or not.

Similarly the study done in Nigeria reported that more than six-tenth of health care workers had poor practice with regards to cold chain monitoring and storage (Jennifer O *et al.* 2017).The other assessments done in 440 storage units found in developed and developing countries, the percent of storage units where vaccines were exposed to temperatures below recommended ranges were 33.3% in wealthier countries and 37.1% in lower income countries (Hanson *et al.*, 2017).

While many of the typical supply chain challenges are exacerbated including improper storage of vaccines, and unsatisfactory knowledge in cold chain management at health facility levels. (Muluken A , Mesganaw F, 2013).

Conclusively, from descriptive result ***insufficient cold chain capacity, lack of latest technology or standard vaccine fridge, knowledge gap of health workers and inadequate temperature monitoring and maintenance system*** found to be the four major influential challenges affecting cold chain management practices.

Whereas interview result show the following challenges Insufficient cold chain ,outdated cold-chain equipment for ultra-low temperature ,wastage increases because of vaccine manage by only shelf life, shortage of vaccines supplies from respective supplies societies were unwilling to take the vaccine.

#### **4.4. COVID-19 Vaccine utilization practices**

Vaccine utilization depends on vaccine availability, the health system capacity to deliver vaccine, the target population Vaccine characteristics and provider and recipient acceptance.

**Table 7. COVID-19 Vaccine utilization practices N=47**

<b>A. Vaccine availability, the health system capacity to deliver vaccine, the target population</b>		Frequency	Percentage
Is COVID-19 vaccine available in your facility?	Yes	44	93.6%
	NO	3	6.4%
The capacity of health care system to deliver the vaccine to potential recipients is sufficient in your facility	Yes	42	89.4%
	No	5	10.6%
Target population, including less than 18 in your facility?	Yes	46	97.9%
	No	1	2.1%
Did your facility faced challenges with utilizing all available doses of vaccines before the expiry date?	Yes	35	74.5%
	No	12	25.5%

Data source: Survey result, 2022

Table 9 indicates that: From 47 health facilities 44(93.6%) had COVID -19 Vaccine and majority health facilities (89.4%) had sufficient health care professionals to deliver the vaccine. Facility faced challenges with utilizing all available doses of vaccines before the expiry date in 35(74.5%)

**Table 8.COVID-19 Vaccine utilization practices**

<b>B</b>	<b>Vaccine characteristics and provider and recipient acceptance</b>	Frequency	Percentage
Characteristics of the vaccine affecting provider utilization	Route of administration	0	0%
	storage conditions	16	34.0%
	shelf-life	31	66.0%
	special procedures required prior to or during vaccination	0	0%
Concern of society about a vaccine?	doubt in safety and efficacy	21	44.7%
	unexpected side effect	14	29.8%
	It is not given for kids	0	0%
	Spiritual issues	12	25.5%

Data source: Survey result, 2022

Regarding to characteristics of the vaccine affecting provider utilization storage conditions challenge occur in 34.0% and shelf life challenge occur in 66.0%.In order to assess the concern

of society about a vaccine doubt in safety and efficacy took 44.7%, unexpected side effect took 29.8%. Spiritual issues took 25.5%.

Based on institute of Medicine (US) Vaccine utilization depend on many interrelated and complex factors includes availability, health system capacity to deliver vaccine, target population and provider and recipient acceptance. In some countries, successful periodic mass immunization campaigns have been conducted, utilizing the mass media and personnel with minimal health training. A study conducted in Lebanon utilization of vaccination services at the national level decreased by 31%. In the private sector, immunization services provision diminished by 46.9% in 2020 (Ziad *et al.*, 2021)

According to Pan American Health Organization vaccine; Vaccine Wastage cause in improper utilization by Losses of inventory (in unopened vials, for different reasons: expiry, damage from cold chain breakdowns, breaking, and freezing). (Pan American Health Organization, 2014)

This study also revealed that utilizing of COVID -19 was society have concern about a vaccine regarding in spiritual issues and side effect of the vaccine. Therefore; the vaccine expired before they take it. It also increases wastage rate. Vaccine does not have VVM like other vaccine so it is challenging to inspect vaccine.

**The third question was, “How COVID 19 vaccine is utilized in your facility and challenges occur in utilization?”**

*EPI focal persons (participant1, 2, 5&6) described about utilization of COVID-19 vaccine: COVID 19 Vaccine was available at the time of study in most of health facility and most facility vaccinated population including less than18years old, with sufficient health care professionals. But there was a problem in vaccine supply as the vaccine was not delivered on time as per the schedule.*

*Other aspect that EPI focal persons mentioned related to challenge with utilizing of COVID-19 vaccine was society have concern about a vaccine in spiritual issues and side effect of the vaccine.*

**Excerpt:** *Participant #7 responds that “We can’t vaccinate societies as our target because societies had a concern about the vaccine*

*Similarly, participant # 4 explained that: “In our facility the societies were unwilling to take the vaccine so the vaccine expired before the society took it. Because of the vaccine manage by shelf life other than expire date”*

*EPI focal (participant (2, 4, 7& 3) mentioned the stock management problem(In most facilities COVID-19vaccine delivery is interrupted that is difficult for appropriate appointment) and insufficient cold chain equipment (For ultra-low temperature refrigeration (Pfizer-BioNTech) COVID-19vaccine there is no standard storage and most facilities had not WHO standard refrigerator in their main medical store).*

Conclusively, the descriptive analysis result and interview results are the same both results indicate as EPI focal persons described about utilization of COVID-19 vaccine through interview.

## CHAPTER FIVE

### SUMMARY, CONCLUSION AND RECOMMENDATIONS

#### 5.1. Summary of the major findings

The researcher aim was challenges of COVID-19 vaccine cold chain management practice vaccine utilization in health facilities under Addis Ababa Health Bureau.

The descriptive analysis indicated the participant's highly practiced on cold chain equipment and slightly practiced regarding on cold chain capacity, stock management and vaccine storage temperature.

The result part challenge affecting Cold chain management practice found to be Insufficient cold chain capacity, Lack of latest technology or standard vaccine fridge, Knowledge gap of health workers and inadequate temperature monitoring and maintenance system influential and Irregularities in electric power supply found to be not influential the cold chain management practice.

Whereas the interview result shows the following challenges insufficient cold chain outdated cold-chain equipment for ultra-low temperature, wastage increases because of vaccine manage by only shelf life, shortage of vaccines supplies from respective supplies, societies were unwilling to take the vaccine.

Regarding Vaccine utilization from 47 health facilities 44(93.6%) had COVID -19 Vaccine and majority health facilities (89.4%) had sufficient health care professionals to deliver the vaccine. Facility faced challenges with utilizing all available doses of vaccines before the expiry date in 35(74.5%). Majority of the respondents faced a challenge in characteristics of the vaccine affecting provider utilization in shelf-life challenge occur in 31(66.0%). In order to assess the concern of society about a vaccine doubt in safety and efficacy took 21(44.7%), unexpected side effect took 29.8%. Spiritual issues took 11.98(25.5%).

Though thematic analysis major themes were resulted in COVID-19 Vaccine utilization challenge insufficient cold chain, outdated cold-chain equipment for ultra-low temperature, wastage increase because of vaccine manage by only shelf life, shortage of vaccines supplies

from respective supplies, COVID-19 vaccine does not have Vaccine Vial Monitoring (VVM) and societies were unwilling to take the vaccine.

## **5.2. Conclusion**

Generally, the cold chain management practices which are cold chain equipment highly practiced while storage capacity, storage temperature monitoring and stock management practice moderately.

On the other hand top challenges was found that Insufficient cold chain capacity, Lack of latest technology or standard vaccine fridge, Knowledge gap of health workers and inadequate temperature monitoring and maintenance system influential.

Related to vaccine utilizing of COVID -19 vaccines was society have concern about a vaccine regarding low knowledge about vaccine in spiritual issues and side effect of the vaccine. Therefore; the vaccine expired before the society took it. This situation also increased wastage rate

## **5.3. Recommendations**

In order to improve COVID-19 vaccine cold chain management practice three things are required. These are personnel, cold chain equipment and stock management. Future more there should be temperature monitoring. Hence the recommendation given will be:

Regarding to COVID-19 vaccine cold chain management practice and for challenges, as it has been observed from the assessment done insufficient cold chain capacity, Lack of latest technology or standard vaccine fridge, Knowledge gap of health workers and inadequate temperature monitoring and maintenance system influential the cold chain management practice. Therefore, there should be supply of additional refrigerators for those who had insufficient cold chain capacity and lack of latest or standard vaccine fridge. In addition AACAHB, Sub city offices and other stakeholders should improve practice in storage capacity should be assessed and assign experienced cold chain equipment maintenance technicians at the facility level. COVID-19 vaccines require special storage temperature monitoring and stock management by using introduction of temperature monitoring and by identify and address logistical issues such as the distribution of adequate storage equipment and give training should be provided periodically to improve stock management and minimize wastage of vaccine.

To improve vaccine utilization ministry of health and AACAHB must create awareness among the society to vaccinate by giving answer for their concern with collaboration of religious organization to decrease vaccine wastage before expire date.

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## Annex1: Questionnaire

Addis Ababa University

School of Pharmacy

Department pharmaceutics and social pharmacy

My name is Betelhem Endale. I am conducting a study on for the partial fulfillment of master's degree in Health supply chain management in Addis Ababa University, School of Pharmacy. The study entitled "***Challenges in COVID-19 vaccine cold chain management practice and vaccine utilization in selected governmental health facilities under Addis Ababa Health bureau***".

Ethical approval and clearance was obtained from Ethical Review committee of school of pharmacy, Addis Ababa University. Supportive letter was obtained from school of pharmacy. Permission to conduct the study was also request from Addis Ababa public health research emergency management directorate. Informed consent will be asked to the study participant to confirm willingness for participation after explaining the objective of the study. The respondents have also the right to refuse or terminate at any point of time. The information provided by each respondent will kept confidential through anonymous recording and coding of questionnaire.

The information that will be collected for this research project will be kept confidential. Taking part in this study you will contribute towards alleviating the problem of poor vaccines management .Should you have any query you can contact the researcher at any time.

Betelhem Endale, Addis Ababa University

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**Questionnaire for the assessment of factors associating with cold chain management of vaccines in selected centers in Addis Ababa**

**Section 1. Socio-demographic characteristics of the respondents**

1. Name of your health facility .....
2. Gender A. Male [ ] B. Female [ ]
3. Work experience A. 1 to 5 years B. 6 to 10 years C) >10 year

**Section 2. Vaccine Cold Chain Management Practice**

Please rate your level of agreement using a 5 point Likert scale Where 1=strongly disagree, 2=disagree, 3=Neutral, 4=Agree 5=Strongly Agree

<b>A</b>	<b>Cold chain equipment and transport</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
1.	WHO standard cold chain fridge vaccine storage is available in the health facility					
2.	Sufficient icepack freezing and storage capacity to meet peak demand is available in the health facility					
3.	Facility have at least one functional refrigerator					
4.	Sufficient cold boxes, vaccine carriers and refrigerator for vaccine storage are available in the health facility					
5.	All refrigerators have a working temperature monitoring device stored with the vaccine (dial thermometer or fridge tag) in the health facility					

<b>B</b>	<b>Cold chain capacity</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
1	The facility has sufficient storage capacity for Covid-19 vaccines					
2	The refrigerator in the health center has functional thermometer					
3	There is alternative storage (e.g., cooler, cold box, other monitored refrigerator) available for vaccine storage, if necessary (e.g., in case of vaccine refrigerator breakdown)					

<b>C</b>	<b>Vaccine storage temperature</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
1	Vaccines are stored in the correct freezing temperature of the freeze sensitive vaccines on the schedule at the health facility					
2	Refrigerated vaccines are presented in temperature between 2-8 °C frozen vaccine present in refrigerator between –(50-15)°C					
3	The refrigerator temperature is recorded twice daily					
4	There is functional thermometer for refrigerator					

<b>D</b>	<b>Vaccine Management (Stock Management)</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
1	All receipts and dispatches are recorded and balances are updated stock record log book					
2	Vaccine requisition forms are used for ordering and receiving vaccine					
3	The vaccine management practice of health facility follows FEFO principle					
4	Expired vaccines are not presented in the refrigerator in the health facility					
5	The vaccine packing area protected from direct sun light in the health facility					

6	Vaccine Vial Monitors status of vaccine is recorded for each vaccine in the health facility					
7	There is no items other than vaccine stored in the refrigerator					

### Section 3. Challenge in Covid-19 Vaccine Cold Chain Management Practice

Please rate your level of agreement using a 5 point Likert scale Where 1=strongly disagree, 2=disagree, 3=Neutral, 4=Agree

A	Insufficient cold chain capacity	1	2	3	4	5
1	Insufficient cold chain capacity negatively affects the availability Cold chain equipment practices of the health facility					
2	Insufficient cold chain capacity negatively affects storage and transport temperature monitoring practices of the health facility					
3	Insufficient cold chain capacity negatively affects stock management practices of the health facility					
B	Lack of latest technology or cold chain equipment					
1	Lack of latest technology or cold chain equipment negatively affects the availability Cold chain equipment practices of health facility					
2	Lack of latest technology or cold chain equipment affects Cold chain capacity practice of health facility					
3	Lack of latest technology or cold chain equipment affects the stock management practices of the health facility					
C	Inadequate temperature monitoring and maintenance system					
1	Inadequate temperature monitoring and maintenance system negatively affects availability cold chain equipment practices of the health facility					
2	Inadequate temperature monitoring and maintenance system negatively affects storage and transport monitoring practices of the health facility					
3	Inadequate temperature monitoring and maintenance system negatively affects cold chain capacity practices of the health facility					
4	Inadequate temperature monitoring and maintenance system					

	negatively affects stock management practices of the health facility						
<b>D</b>	<b>Knowledge gap of health workers</b>						
1	Knowledge gap of health workers negatively affects availability Cold chain equipment practices of the health facility						
2	Knowledge gap of health workers negatively affects Storage and transport temperature monitoring practices of the health facility						
3	Knowledge gap of health workers negatively affects cold chain capacity practices of the health facility						
4	Knowledge gap of health workers negatively affects stock management practices of the health facility						
<b>E</b>	<b>Irregularities in electric power supply</b>						
1	Irregularities in electric power supply negatively affect Cold chain equipment practices of the health facility						
2	Irregularities in electric power supply negatively affect cold chain capacity practices of the health facility						
3	Irregularities in electric power supply negatively affect stock management practices of the health facility						
4	Irregularities in electric power supply negatively affect storage and transport temperature monitoring practices of the health facility						

#### Section 4.COVID-19 vaccine utilization

1. Is COVID 19 vaccine available in your facility? A. yes B. No
2. The capacity of the health care system to deliver the vaccine to potential recipients is sufficient in your facility?  
A. Yes B. No
3. Target population, including under 18in your facility?  
A. Yes B. No
4. Characteristics of the vaccine affecting provider utilization

A. Route of administration B. storage conditions C. shelf-life D. special procedures required prior to or during vaccination

5. Concern of a society about a vaccine?

A. doubt in safety and efficacy B. Unexpected side effect C. It is not given for kids other please specify

6. Did your facility faced challenges with utilizing all available doses of vaccines before the expiry date. A. Yes B. NO

**Section 5: Interview open ended question**

1. How COVID 19 vaccines cold chain management practice in your health facilities?"

.....  
.....

2. What are the major challenges in COVID 19 vaccines cold chain management practices in your health facility?

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3. How is COVID 19 vaccine utilization in your facility challenges occur in utilization?"

Any comment:

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## Annex2: List of selected health facilities

S.N	Facility Name	Sub-city	Number of Health centers
01	Genbot 20 HC		
02	Woreda 3 HC	Addis ketema	04
03	Addis Ketema HC		
04	Abisiniya HC		
04	EntotoFana HC		
05	Maychew HC		04
06	Shiromeda HC	Gullele	
	Hiddase HC		
07	Woreda 5 HC		04
08	Woreda 6 HC	Nifasilk	
09	Woreda 9 HC		
	Woreda 2 HC		
10	SelamFiree HC	A.kality	04
11	Akakikela HC		
12	Gelan HC		
13	Kality HC		
14	Mesulekia HC	Kirkos	04
15	Kazanchis HC		
	HiwotAmba HC		
16	Kirkos HC		
17	Woreda 1 HC	Yeka	04
18	Entoto No.1 HC		
	Kotebe HC		
19	Yeka HC		
20	Goro HC		
21	Amoraw HC	Lemikura	04
22	Semit HC		
23	Meri HC		
24	DagimHidasea HC	Lideta	
25	Lideta HC		04
26	Belteshachew		
28	Abinet HC		
29	Gerji HC	Bole	
30	Dilfire HC		04
31	Addis Hiwot HC		
32	Bole Chefe HC		

33	KolfeWoreda 1 HC	Kolfe	04
34	KolfeWoreda 6 HC		
35	KolfeKeraniyo HC		
36	Kebena HC	Arada	
37	Arada HC		
38	Jan Meda HC		
39	AfinchoBer HC		04

1.Yekatit	Hospital
2.Minilik II	Hospital
3.Ras Desta	Hospital