

COLDCHAIN PHARMACEUTICALS STORAGE AND DISTRIBUTION PRACTICES IN PUBLIC HEALTH FACILITIES IN BENCH-SHEKO ZONE, SOUTHWESTERN ETHIOPIA

BY:

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A RESEARCH THESIS SUBMITTED TO JIMMA UNIVERSITY; INSTITUTE OF HEALTH, SCHOOL OF PHARMACY; FOR PARTIAL FULFILLMENT FOR THE REQUIREMENTS OF MASTER OF SCIENCE DEGREE IN PHARMACEUTICAL SUPPLY CHAIN MANAGEMENT

> MARCH, 2022 JIMMA, ETHIOPIA

JIMMA UNIVERSITY INSTITUTE OF HEALTH SCHOOL OF PHARMACY

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Declaration

This is to declare that the research paper entitled "Cold chain pharmaceuticals storage, and distribution practices in public health facilities in Bench-Sheko Zone, Southwestern *Ethiopia*" is done by Fikere Alemayehu

I, Fikere Alemayehu also declare that this research is my own original work and that all sources of materials used for the study have been properly acknowledged.

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Acronyms

CDC- Center for Disease Control

EFDA- Ethiopian Food and Drug Act

EFMHACA- Food, Medicine and health care Administration and Control Authority of Ethiopia

EPI- Expanded Program of Immunization

EPSA-Ethiopian Pharmaceutical Supply Agency

FEFO- First Expiry First Out

FMOH- Federal Minister of Health

LIAT- Logistics Indicators Assessment Tool

LSAT- Logistics Systems Assessment Tool

NGOs- Non-Governmental Organizations

SOP- Standard Operating Procedures

SPSS- Statistical package for the social sciences

USAID- United States Agency for International Development

VVM- Vaccine vial monitor

WHO- World Health Organization

Abbreviations

CC- Cold Chain CCM- Cold chain management CCPs- Cold chain pharmaceuticals DFs- Deep Freezers HCs- Health Centers ILR- Ice lined Refrigerator KI- Key Informant OPD- Out Patient Department PHCs- Primary Health Centers PHFs- Public Health Facilities PI- principal Investigator SNNPR- Southern Nation, Nationality and People Region UPS- Uninterrupted Power Supply

Abstract

Background: Appropriate storage and distribution practices are essential to maintain quality products to protect patients from consuming ineffective cold chain pharmaceuticals. However, there is limited evidence on cold chain pharmaceuticals practices in this study area. Therefore, the study aimed to assess cold chain pharmaceuticals storage and distribution practices in public health facilities in Bench-Sheko Zone, Southwestern Ethiopia. **Method:** Concurrent explanatory mixed method was conducted from October 1 to November 30, 2020. Data were collected from 25 public health facilities using tools adapted from World Health Organization, logistics indicators assessment tool and logistics systems assessment tool guideline. Data were cleaned, processed and entered in to the Statistical Package for the Social Sciences version20. The chi-square test was done to identify the association at a p-value of 0.05 significant levels. For the qualitative data analysis, 12 key informants were interviews for 15-20 minutes and analyzed using thematically. Lastly, triangulation of the qualitative findings with quantitative carried out.

Results: Twenty-five public health facilities participated in the study with response rate of 92.6%. Only 25% of good storage practice and 27.63% distribution practice of cold chain pharmaceuticals at public health facilities fulfilled the World Health Organization and USAID delivery guide respectively. Mainly the practice was poor due to the result is below 80% of World Health Organization criteria. Similarly, the chi-square test indicated that the association between storage and distribution practice with independent variables Such as work experience $X^2(2, N=76)=26.65$, p=0.009, training $X^2(1, N=76)=10.72$, p=0.005, supervision $X^2(1, N=76)=3.82$ p=0.014, was statistically significant. This result was also supported by the majority of key informants that identified lack of pharmacy professionals, shortage of infrastructure and equipment, low supervision and training was claimed to be challenged in cold chain pharmaceuticals management.

Conclusion and recommendations: The storage and distribution practice of cold chain pharmaceuticals was poor that is associated with the work experience, training and supervision. Therefore, there should be continuous professional education, training, supportive supervision, availability of equipment and infrastructure required for proper storage and distribution practice. Hence, the Zonal health department, woreda health office, and health facilities should collaborate to improve cold chain pharmaceuticals practices for quality services. **Key words:** Cold chain pharmaceuticals, Distribution, Practice, Public health facilities, Storage

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1. Introduction

1.1. Back ground

Cold chain (CC) is a system of storing and transporting cold chain pharmaceuticals (CCPs) at recommended temperature range from the time of manufacture until the point of end-users. However, product quality is guaranteed within the World Health Organization (WHO) guideline for proper storage and distribution of CCPs at different temperatures. The temperature monitoring device ensures that temperatures vary from +2 °C to +8 °C, which can be monitored by all health workers in all supply chains, from production to end consumers. Cold chain temperatures consist cool 8°C to 15°C, cold/refrigerated 2°C to 8°C oxytocin, insulin, DTP hepatitisB-Hib (pentavalent), Tetanus toxoid(TT),freeze -15°C to -25°C. And CCPs also include immune globulin, serum, ergometrine, antirabies, blood products and certain kits of laboratory tests. Specifically, vaccines that are sensitive to light as they are to heat includes OPV, Bacillus Calamette Guerin (BCG),and measles whereas deep freeze is greater than -25°C (1–3). Particularly products that have not been maintained at an appropriate temperature and under the proper conditions during storage and distribution are considered to be unsafe for use (4).

Cold chain management (CCM) is essential to ensure the right quality is maintained throughout the supply chain by standardized guidelines that function around the world. Adhering to these standards is difficult due to the different climatic conditions which are a huge challenge for CCM. Proper CCM has been an important factor in the prevention and eradication of many common diseases preventable by vaccines. Storage, handling and distribution errors can reduce potency and effectiveness result in many clients being revaccinated. Failure to store and maintain proper management of CCPs may reduce potency that results in poor protection of disease. Moreover, the failure of storage and distribution conditions of CCPs leads to cost thousands of dollars, and wastage of products. Clients can lose confidence in vaccines and immunization service providers if they have to be revaccinated after receiving vaccines that may have been compromised (3).

CCM is important to ensure that clients receive elective health products, including vaccines that have not been adversely affected by heat or cold. CCM is used to prevent wastage of expensive CCPs. It also enhances efficient vaccine storage and distribution to keep in good quality, assurance measure of an immunization service provider. CC including vaccines must be stored and transported within the recommended temperature range of $+2^{\circ}$ C to $+8^{\circ}$ C at all

times because most vaccines are destroyed by freezing, and some vaccines are also particularly sensitive to heat that needs well management CCPs. Mainly, there are three major components of the CCs essential, namely well-trained staff, reliable transportation/ storage facilities, and efficient management procedures that are required to effectively manage CCP. Lack of any of these would lead to poor cold chain management (1,3). Moreover, health facilities in developing countries are supposed to maintain the cold chain to ensure that temperature-sensitive medicines reach consumers of good quality (5). Similarly, the guideline of the Ethiopian Food and Drug Act (EFDA/formerly EFMHACA) specifies that the CCPs be stored under conditions that minimize degradation, or damage that must be stored under conditions that are compatible with their recommended storage requirements (6). Throughout efforts to prevent preventable diseases, Proper storage and handling of CCPs play critical roles. Therefore, the Center for Diseases Control (CDC) has advised storage, managing procedures and providers should ensure that patients receive uncompromised highquality CCP (7).

Distribution is an important activity in managing CCPs integrated supply-chain. An individual or entity is, in any case, only involved and accountable for certain elements of the distribution process. Hence, appropriate storage and distribution are essential to maintain quality and to protect patients from consuming inefficient CCPs. However, CC monitoring is the main challenge in developing countries, mainly in Ethiopia, due to poor transportation infrastructure, unreliable electricity sources, shortage of trained personnel, and lack of adequate equipment that weakens cold chain management (8). CCPs are costly and shortly supplied particularly in rural communities where transportation systems are in adequate. Besides, all personnel along the supply chain are required to implement proper handling of temperature data loggers that provide valuable information in a convenient format including temperature, humidity, time and date recording as the main monitoring components (5). In addition maintaining the cold chain is the backbone for the effectiveness of CCPs for quality service to prevent disease (9). In some cases, failure in one or another of these components causes the failure of the cold chain (7).

The pointers or guiding principles for good pharmacy practice standards for the distribution and storage set up by USAID|DELIVER PROJECT, such as logistic indicator assessment tool (LIAT) is the developed and widely applied instruments in assessing the storage and distribution of CCPs (10).

Besides, the LIAT result greater than 80% positive response is considered as for good storage and distribution. According to CDC, good vaccine storage and handling include storage of vaccines between 2 and 8^oC with a temperature monitoring twice daily, use of stand-alone refrigerator, the dedication of the vaccine storage for vaccine only (no food, beverages, or other substances), keeping vaccines 2-3 inches away from walls and other boxes. After reviewing the literature, it has been discovered that there was a limited study that focuses on the storage and distribution practice of CCPs in the Bench-Sheko Zone, Southwestern Ethiopia. As a result, this study aims to add to the existing knowledge of the storage and distribution practice of CCPs from Ethiopia's perspective especially at Bench-Sheko Zone, Southwestern Ethiopia.

1.2. Statement of the problem

CCPs are temperature sensitive product and lose their potency if they are exposed to temperatures outside $+2^{\circ}$ C to $+8^{\circ}$ C, heat, freeze or light. CCM enhances efficient cold chain storage and distribution to keep in good quality, assurance measure of an immunization service provider. Similarly, reduces re-vaccination of clients, increases clients' confidence in vaccination, prevents wastage of expensive CCPs and protect poor management (1,3). This errors can also cause in the loss of potency of medicines may lead to increased disease burden, medical costs to patients, and wastage of supplies. Moreover, the lack of availability and consistent storage procedures, lack of usable Cold chain equipment due to power breakdown, lack of trained professionals,, unreliable standard power source and shortage of infrastructure including transportation leads to the cold chain failure (7,11).

The consequence of this failure caused for extra doses for patients, cost thousands of dollars for providers, reduces clients confidence in cold chain products, increases wastage of products, and expiry due to poor CCM (12). Moreover unreliable electricity, and shortage of equipment, manpower and knowledge were affected CCPs practices in developing countries especially at the lower level healthcare facilities (13). The maintenance of vaccine cold chain requires adequate cold chain infrastructure, trained staffs and compliance to standard. But evidences show that trained personnel in charge of vaccine cold chain are commonly available in developed countries than developing country. Studies also reported that the cold chain system is assumed to be at greatest risk, particularly in countries where power supply is unreliable and facilities for its maintenance are not well developed (8). Proper cold chain management is a major challenge of worldwide; CCPs are costly and shortly supplied particularly in rural communities where transportation systems are inadequate (5). A study showed that lack of adequate infrastructure, high cost of implementation costs was affect storage and distribution practices (14). As a result, the failure of CCM leads to reduce the vaccine potency, resulting in inadequate immune responses in clients and poor protection against preventable disease. To maintaining cold chain pharmaceuticals, it requires trained professionals, adequate cold chain infrastructure, and equipment compliance to standard. But evidences show that not met standard. A study finding from Chhattisgarh Central India's reported that 20% of cold chain points, where CCPs were stored and managed were found in the frozen state. Besides about 75% availability of functional thermometer that had 65% temperature within the recommended range. Similarly, temperature monitoring was only observed in 95 % CCPs twice daily. Whereas about 70% record of power failures and

defrosting was noted in temperature logbooks and the correct placement of ice packs inside the deep freezer was observed at only one cold chain point (15). Another Study reported from Ahmedabad municipal corporationhas shown that 12.5% of health facilities don't record temperature due to power failure and 41% defrosting status found in the record book (16). Proper cold chain management is a big challenge in storage and distribution of CCPs particularly in developing countries: due to, unreliable electricity, shortage of equipment, manpower and knowledge was affected CCPs practices in developing countries especially at the lower level healthcare facilities (13). Storage is a critical parameter for preserving the efficiency, protection, stability, and efficacy of CCPs and must be stored following the requirements. One of the common components constraining full and impartial immunization in numerous countries, the lack of appropriate storage and transport temperatures particularly for vaccines (13). Moreover, in cases of outbreaks of vaccine- preventable diseases especially measles has been reported in some areas in the country due to elevated temperature of CCPs maintenance. A similar study from the North-West region of Cameroon has revealed that 33.9% of health facilities had no EPI guidelines. About 26.9% of the health facilities report at least one elevated temperature over the last 2 months following data collection. But 28.3% of personnel did not know the correct vaccine storage temperature (11). The evidence from Tanzania indicated that 48.5% of healthcare facilities visited did not meet storage temperature significantly, $+2^{\circ}$ C to $+8^{\circ}$ C, as per the requirement of WHO that reported greater than 8°C (17). Similarly, A study from Ghana reported that none of the facilities assessed met the WHO benchmark of 80% for all. About 60% of temperature control, 32% of Stock management and only 27% effective vaccine distribution and practices ineffective CCM (18). The research findings from Cameroon identified that at one point 83% of shipments were exposed to freezing. About 51% of freeze exposures were the maximum at the facility level during storage, followed by 31% at the district level where the minimum temperatures reached ranged from -0.5°C to -23.8°C. Unlike freezing, at one point both means of transport were exposed to temperatures above 8°C. Around 96 percent of shipments have been exposed for over 10 hours to temperatures above 8°C. Transportation was a major contributor to exposures both heat and freeze. The use of outdated and uncertified cold chain equipment and practices were important contributors to unintended exposures (19).

A similar study from Ethiopia, the Amhara region East Gojam zone reported that 76.7% had functional refrigerators. Likewise, about 35% had a functioning generator for backup service and 46.6% had a car/motorbike for vaccine transport in case of refrigerator/ power failure. In addition, the finding revealed that 48.3% had known the correct storage temperature of the

vaccine (2 °C to 8 °C) in the refrigerator. In addition, the study showed that approximately 58.3% had acceptable CCM practice showing the gap in professions was significantly associated with CCM practice (20). Another finding from Nekemte town, Western Ethiopia revealed that below half, (44.4%) of respondents were practicing the recommended temperature range for most cold chain medicines stored in refrigerators (21). Currently, there is a problem of electricity which is unreliable and large areas of rural do not have electricity. Studies suggest that as recommended by WHO 50% of health facilities regularly fill their temperature charts twice a day. Evidence has shown that about 26.9% of the healthcare facilities record at least one abnormal temperature (11,22). Moreover, the lack of availability and consistent storage procedures, usable CC equipment as well as trained personnel leads to the CC failure(7). Some studies showed that there was poor CCM among health professionals working in health facilities. Mainly, due to a shortage of longer work experience, in-service training, and the use of EPI guidelines at work were primary factors. To improve health professionals good practice about CC management, that needs to be maintained (23,24). Similar studies indicated problems with proper storage and gaps to maintain the recommended CC system. Research in Bale Oromia, Ethiopia, indicated that 30.6% of health facilities had a refrigerator. About 57.1% had national cold chain monitoring guidelines and 40% stored vaccines properly. However, the required temperature range for storage was answered correctly by around 67.8 percent of vaccine providers (8). At public health facilities, improving practice is vital to the success of providing safe and quality CCP to enduser. Considering this, it would be important to know how PHFs have developed their cold chain practices and how they performed. Up to the present time, limited research has been carried out in storage, and distribution of CCP in a study area at public health facilities. Hence this paper would help to bridge the literature gap in this area. The present study, therefore, helps to identify the inappropriate practice of storage and distribution of CCPs, management gaps in cold chain equipment and infrastructures, and challenges of cold chain practices at public health facilities in Bench Sheko Zone, Southwestern Ethiopia.

1.3. Significance of the study

The study assessed the storage and distribution practices of cold chain pharmaceuticals in public health facilities in the Bench-Sheko Zone, Southwestern Ethiopia that could have several contributions. The study findings and suggestions could be useful for the Bench-Sheko Zone, to improve the storage and distribution of CCPs. This study can help to identify management gaps in cold chain equipment and infrastructures, and inappropriate practices challenges during storage and distribution. The result of the study can help, to FMOH, EPSA, regional health bureau may find results of this study of importance to reassess the practice again and to develop policies that ensures efficient practices and improve the quality of CCPs, to formulate strategic plans for gaps in CCM, to know the current status of the study area, to show future professional and policy direction. To health facilities the result may be used by the management of each public facility in making decision on way of improving their practice. To health professionals' the assessed practice and challenges findings may be used by professionals and a guide for the study areas. Therefore, appropriate and effective storage, and distribution of CCPs is vital to prevent cold chain failures at a service level. It may also serve as the basis for further large-scale studies across the region as well as country on cold chain pharmaceuticals.

2. Literature Review 2.1.Over view

Cold chain is the system used to store and transport cold chain pharmaceuticals within a temperature range between 2° C to 8 °C and freezers -15 to -25°C in good condition. To preserve product quality, from time of production to end-user by ensuring that cold chain pharmaceuticals are stored and transported within the temperature ranges specified by WHO. It is important that all those who handle vaccines and diluents know the temperature sensitivities and the required storage temperatures for all national vaccines (1–3). CC is a temperature-controlled system that includes all cold chain-related equipment and procedures. The cold chain starts with the cold storage unit at production, continues to the CCPs transport, distribution, and appropriate storage at the provider facility, and ends with the patient's CCPs administration. If the cold chain is not maintained properly, vaccine potency may be lost, leading to a useless supply of the vaccine. Each time a vaccine is exposed to an improper condition; potency is reduced. This includes over-exposure to heat, cold, or light in the cold chain at every step (3). Potency cannot be recovered once it has been lost. Although exposure to unsafe conditions can affect the potency of any refrigerated vaccine, a single exposure to freezing temperatures (0°C) can destroy the potency (3,7)

Cold chain management

CCM is essential to ensure the right quality is maintained throughout the supply chain by standardized guidelines that are function around the world, focusing mainly on the proper storage and transportation. Adhering to these standards is difficult due to the different climatic conditions which are a huge challenge for CCM. CCP is very temperature sensitive when exposed to light, permanently losing potency and effectiveness if debited from the recommended ranges. Proper storage and handling of vaccines have been an important factor in the prevention and eradication of many common diseases preventable by vaccine storage, handling and distribution errors can reduce the potency and effectiveness results in many clients being revaccinated (3). Failure to store and maintain properly incorrect management of cold chain pharmaceuticals may reduce the vaccine potency, resulting in inadequate immune responses in clients and poor protection against disease. Moreover, leads to cost thousands of dollars, wastage of products, and expiry. Clients can lose confidence in vaccines and immunization service providers if they have to be revaccinated after receiving vaccines that may have been compromised (12).

Importance of cold chain management

Cold chain management is vital to ensure that clients receive effective health products, including vaccines that have not been adversely affected by heat or cold. CCM enhances efficient vaccine storage and distribution to keep in good quality, assurance measure of an immunization service provider. Similarly, reduces re-vaccination of clients, increases clients' confidence in vaccination, prevents wastage of expensive CCPs and poor vaccine management. Cold chain must be stored and transported within the recommended temperature range of $+2^{\circ}$ C to $+8^{\circ}$ C at all times because most vaccines are destroyed by freezing, and are also particularly sensitive to heat. Therefore, cold chain management to be well-organized (1,3). CCM is important in the prevention and eradication of many common diseases preventable by vaccines. Effective CCM improves the vaccine potency, high protection against disease. Moreover, prevents thousands of dollars cost, wastage of products, expiry (3). Maintaining the cold chain management is the backbone for the effectiveness of the disease prevention and control program, and therefore there is a critical need to ensure a reduction in morbidity and mortality worldwide (9).

Cold chain pharmaceuticals

cold chain pharmaceuticals include such as oxytocin, insulin, vaccines, immune globulins, serums, ergometrine, blood products, and some set of laboratory tests, etc. (4). CCPs are temperature sensitive and lose their potency if they are exposed to temperatures outside the required range of $+2^{\circ}$ C to $+8^{\circ}$ C or when exposed to light. Loss of potency of medicines may lead to increased disease burden, medical costs to patients, and wastage of supplies. Biopharmaceuticals are expensive and often in short supply, particularly in rural communities where transport systems are inadequate (7,11) Therefore, during the transport, storage, and handling of CCPs, CC maintains optimal conditions.

Cold chain equipment

The national cold chain system requires various types of equipment for the transport and stora ge of CCP including vaccines and diluents within the appropriate temperature range, depending on the capacity needed. In addition, health care facilities require cold chain equipment such as ice-lined-refrigerators, ice-packs, deep freezers, temperature monitoring device, cold boxes and vaccine carriers. Cold chain equipment is needed at health facilities. CCM is an essential system for controlling CCPs to ensure that the expected quality of the products provides patients with high-quality services. But at various point, different factors weakens or influence CCM, from manufacturing to end-users. Mainly CCM is

affected by different factors such as socio-demographic characteristics of health professionals, storage conditions, distribution, availability of equipment, and infrastructure.

2.2. Socio-demographic characteristics

Competent personnel are important in the distribution and storage activities of temperaturesensitive products based on written standard operating procedures (SOPs). A study conducted from primary health care facilities in Niassa, Mozambique, revealed that to fill the gap of cold chain practices especially in the peripheral level workers to improve knowledge and practice by providing them with adequate training and supervision, and demonstrating how that can be effectively integrated with practice(15). A similar study from south-west Burkina Faso stated that improved staff training and monitoring are immediate responses for recommended temperature and effective immunization coverage in addition to the renewal of the cold chain infrastructure (25). The practitioners' experience in how temperature-sensitive products are stored and distributed throughout the length of the distribution system is paramount for quality CCP services. A study conducted in the Gurage zone has shown 51.3% of health professionals had satisfactory knowledge about cold chain management. Also indicated being trained on immunization program having a work experience above six years using EPI guidelines and being a BSc nurse/health officer had got better knowledge on cold chain management. Health professionals working in the health centers had low knowledge of cold chain management (23).

2.3. Storage practice related

CCPs are sensitive biological substances that can easily be affect when don't store properly. Due to improper storages and distribution, the products lose their potency or are less effective. CCPs stored in the refrigerators included: different vaccines; insulin, oxytocin, ergometrine, antirabies etc.

A study from Ghana reported that none of the facilities assessed met the WHO benchmark of 80% for all. About 60% of temperature control, 32% of Stock management and only 27% effective vaccine distribution with poor knowledge and practices in effective CCM (18). A similar study from the North-West region of Cameroon has revealed that 33.9% of health facilities had no EPI guideline but had 50% correctly filled temperature chart in 96.2% health facilities. About 26.9 percent of the health facilities report at least one elevated temperature over the last 2 months following data collection. But 28.3% of personnel did not know the correct vaccine storage temperature (11). Another study done in Damoh district of Madhya

Pradesh stated that 73.9% of the health professionals had good practice of CCM (26). Lack of proper practice by Health professionals in the control of storage and transportation temperatures can have a major impact on product quality. A study conducted among health workers in primary health-care facilities in Edo State Nigeria, had shown gap in CCM among the respondents,64.0% had poor practices (24). The findings from Giwa, Northwestern Nigeria have shown 71.8% of the respondents knew the correct temperature range for which vaccines should be stored. About 75.6% of the respondents agreed that cold chain management is important but only 51.3% of the respondents had appropriate practice (27).

The studies reported from Nigeria, Oyo State 73% were aware of vaccine handling and storage guidelines with 68.4% having ever read such guidelines. Only 15.3 percent read a guideline less than one month before the study. Approximately 65.0% had received training on vaccine management and 7.6% maintaining vaccine temperature using ice packs. Approximately 43.0% had good information on vaccine management, while 66.1% had good vaccine management practices (28). Another finding from Nekemte town, Western Ethiopia revealed that 59.6% of workers were ever attended training on storage, distribution and handling procedures of cold chain medicines. However, the national guidelines recommend the storage temperature of most vaccines is between $+2^{\circ}$ C to $+8^{\circ}$ C, only about 44.4% of respondents were practicing the recommended temperature range for most cold chain medicines stored in refrigerators. About 69.7% of the respondents said that storage device is equipped with thermometers. Similarly, the study indicated that in most of the health care facilities 56.25% had a thermometer in the refrigerator. Temperature monitoring being recorded was not statistically significant difference with the compliance with storage temperature (21).

A study from Bale Zone, southeast Ethiopia has shown 30.6% of health facilities had refrigerators, 57.1% had national cold chain monitoring guidelines and only 40% stored vaccines. Similarly, 82.86% of refrigerators thermometers showed temperature readings within the standard range (2°C-8°C). About 67.8% of vaccine providers have responded correctly to the recommended range of temperature for storage (8).

2.4. Distribution practice related

The distribution process focuses on delivering CCPs at the right time and in the right quantities to satisfy demands from the health facility. Distribution of the cold chain can add to the efficiency of the CCPs by reducing the transportation time and the overall costs.

Effective CCPs are characterized by the timely and reliable distribution of CCPs and information to health facilities from the service delivery point. The study indicated gaps in maintaining cold chain storage and improper distribution that compromise the potency of the CCP and the quality of the services. The research findings from Cameroon identified that at one point 83% of shipments were exposed to freezing. About 51% of freeze exposures were the maximum at the facility level during storage, followed by 31% at the district level where the minimum temperatures reached ranged from -0.5°C to -23.8°C. Unlike freezing, at one point both types of transport were exposed to temperatures above 8°C. Around 96 percent of shipments have been exposed for over 10 hours to temperatures above 8°C. Transportation was a major contributor to exposures both heat and freeze. The use of outdated and uncertified cold chain equipment and gaps in healthcare worker knowledge, and practices were important contributors to unintended exposures (19).

According to the Federal Ministry of Health (FMOH) work has been to ensure efficient and high performance healthcare that guarantees equal access for all Ethiopians to affordable medicines. Significant progress has been made in recent years; EPSA is attempting to improve pharmaceuticals proper quality, quantity and affordable price distribution. But specific problems remain, including an inadequate supply of quality and affordable essential pharmaceuticals, poor storage conditions, and weak stock management resulting in high levels of waste and stock-outs (29).

Pharmaceutical distribution in Ethiopia has several challenges including undefined stock quantity as available, report interruption and delay, some items reported as stock out during biweekly report but not requested/needed when the facilities bring their request, use of quick win plan to fulfill the routine task that was performed by drug supply management (30). The study from the East Gojam zone of the Amhara region, Ethiopia, revealed that about 58.3% had appropriate vaccine cold chain management practice and 41.7% had inappropriate practice (20).

2.5. Availability of infrastructure and cold chain equipment

Several responsible factors for CCPs in developing countries are unreliable electricity, and a shortage of resources like equipment, and manpower (11). To prolong the shelf life of CCPs temperature monitoring devices are the most important factor to ensure quality and safety. The study from south-west Burkina Faso reported, there is an adverse temperature were recorded 83% of refrigerators and ranged from 10% abnormal hourly records below +2 C and

5.7% above +8 $^{\circ}$ C (25). However only 57.6% of cold chain handlers could demonstrate the correct way of reading the thermometer and only 11.6% knew when and how to conduct a shake test. Only 69.2% of CC handlers carried out the conditioning of ice-packs as per the guidelines in District Meerut, Uttar Pradesh, India (31).The similarly 66.66% ice lined refrigerator and deep freeze were connected to functional voltage stabilizer in community health centers with 100% availability of the functional thermometer were about 66.66% of community health centers record temperature twice daily (26).

The findings have shown only 57.14% and 71% of cold chain points had dedicated space for dry storage and conditioning of ice packs respectively. Similarly, 50% cold chain points had correct placement of ice-packs inside deep freezers with 86% functional thermometers inside every equipment available that 93% of temperature record twice daily within normal range. Record of power failures and defrosting/cleaning in temperature log-books was found in 57% and 43% correspondingly in which 43% temperature log book was countersigned by the facility in charge (32). The study results from Cebu, Philippines indicated that storage units and equipment were available in all 22 PHCs with 22.7% stored vaccines. About 90.9% of PHCs did not have an access to a generator and only 9% had a voltage stabilizer connected to the refrigerator. About 68.2% of refrigerators were equipped with the thermometer in PHCs (33). The study finding from Bahir dar revealed that9 total health facilities (64.3%) have an effective thermometer, 14 (100%) have refrigeration sources, and 10 (71.4%) have an efficient copy-generating generator. 9 (64.3%) had a guide line in place. At 10 health facilities (71.4%) monitor the temperature twice a day at that facility. Among the features, only work experience and level of knowledge about the control of the vaccine chain have a statistically significant relationship with the practice of health workers in controlling the cold chain(34).

2.6.Conceptual framework

The conceptual framework of this study was developed after reviewing related sources such as article, guidelines, systematic reviews, books, and other materials based on the objective of the study to show the current storage and distribution practices of cold chain management. It includes socio-demographic factors, Storage & distribution-related factors, and availability of CC equipment and infrastructure. By reviewing different articles, guidelines and related sources the following conceptual framework was prepared for this study (Fig 1).



Key: -CC- Cold chain, CCPs- cold chain pharmaceuticals, CCM - Cold chain management,

ILR-Ice lined refrigerator, SOP-Standard operating procedure

Figure 1.Conceptual framework: Adapted from reviewing different literature and related sources by PI.

3. Objectives of the study

3.1. General objective

The general objective of the research was to assess cold chain pharmaceuticals storage and distribution practices in public health facilities in Bench-Sheko Zone, Southwestern Ethiopia.

3.2. Specific objectives

- To assess the storage practice of CCPs at public health facilities in Bench-Sheko Zone.
- To assess the distribution practice of CCPs at PHFs in Bench-Sheko Zone.
- To explore the challenges of CCM at public health facilities in Bench-Sheko Zone.

4. Methods

4.1.Study area and period

The study was conducted at Public Health Facilities (PHFs) in Bench-Sheko zone, Southwestern Ethiopia. Bench Sheko zone is previously known as Bench Maji Zone found in the Southern Nations, Nationalities, and Peoples' Region (SNNPR) of Ethiopia. The zone is located 582 kilometers away from the capital city of Addis Ababa and 853 km from Hawassa the capital city of SNNPR. It is bordered by the Kaffa zone in the south, Sheka zone in the North, Gambela Region in the west, and South Omo in the East. According to the Bench-Sheko zone socio-demographic and socio-economic report, the zone has a total population of 625,345. There are 309,755 men and 315,590 women living in the Bench-Sheko zone. There are six woredas and two city administrations. The zone has one teaching and referral hospital. Similarly, there are 26 health centers and 128 health posts serving the community (35). The study was conducted from October 01 to November 30, 2020, in PHFs in Bench-Sheko zone, Southwestern Ethiopia.

4.2.Study design

A facility-based concurrent explanatory mixed method strategy for quantitative design and phenomenological study design for qualitative was used to assess cold chain pharmaceuticals storage and distribution practices for this study.

4.3. Population

4.3.1. Source population

The source population for this study was all public health facilities, all health professionals, all cold chain products, and all documents used in managing CCPs in public health facilities in Bench Sheko zone, Southwestern Ethiopia.

4.3.2. Study population

The study population was selected health professionals involved in cold chain pharmaceuticals management, selected key informants from health professionals, selected key cold chain products (tracer vaccine such as BCG, OPV, Penta, TT Vaccine, PCV, Measles vaccine, Rabies vaccine, TAT, Oxytocin, Ergometrine, Insulin, HIV Beiging Wental Khaletra (Lopinavir/Retinovir fixed dose combination) and selected public health facilities during the data collection period were considered for the study.

4.4. Inclusion and exclusion criteria

4.4.1. Inclusion criteria

This study includes all public health facilities that manage cold chain pharmaceuticals. In this sense, six months of records on CCPs were reviewed to obtained adequate evidence and to check temperature monitoring relevant documents in public facilities. Similarly, experienced and positioned health professionals in selected public health facilities for qualitative method were considered in this study.

4.4.2. Exclusion criteria

This study excluded health extension workers serving in health posts, because they did not manage all essential CCPs and they were under the umbrella of health centers. Likewise, health professionals who were unwilling to participate and out of service during the study period were excluded from the study.

4.5. Study variables

- 4.5.1. Dependent variable
- Storage practice
- Distribution practice
 - 4.5.2. Independent variable

Socio-demographic characteristics

- Profession
- Qualification
- Work experience
- Supervision
- Training

Availability of cold chain equipment and infrastructures

- Refrigerators
- Freezers
- Cold boxes ,vaccine carriers, ice pack & foam pad
- Thermometers/fridge tags
- Type of transport
- Store rooms
- Electricity power source
- Power backup(Generator/Solar)

- Voltage stabilizers
- SOP/EPI guidelines

Storage practice related to health worker

- Facility (cold Storage room)
- Personnel(professionals)
- Recommended temp.ranges
- SOP availability
- Power interruption
- Maintenance of equipments
- Availability of spare parts
- Supportive supervision

Distribution practice related to health worker

- Special transportation vehicles
- Monitoring device
- Guideline for transportation
- Documentation
- Schedule for distribution
- Insulated containers(Coolers)
- Availability of spare parts

4.6. Sample size determinations and sampling techniques

The study area has 24 health centers and 1 teaching hospital (76 cold chain points), all of them were included in the study. Besides six- month temperature monitoring charts and log books were taken to review data to check CCPs recording system. Moreover, from the health facilities, three cold chain points from HCs (store, EPI & dispensers) and four cold chain points including the MCH unit from the hospital were considered for data collection that accounts 76 cold chain points for quantitative study. Twelve Key informants were selected purposively interview by considering their work experience and position on CCM until it reaches saturation of ideas for qualitative. Specifically, the participants were three storeman, four EPI focal persons, and five pharmacy heads were selected purposively.

4.7. Data collection procedures

The data collection was carried out from October 01 to November 30, 2020. Purposively twelve key informants were selected from health facilities that are health care providers based on experience and position for qualitative. Total of 76 cold chain points were selected for quantitative. Then, structured questionnaires and checklists adapted from USAID delivery Project tools (LIAT) were used to collect data from the store manager, dispensers, and EPI focal person using the English version (10). In the same way, four checklists and document reviews were used to assess the functionalities of cold chain equipment at the PHF (annex 4). Storage and distribution of cold chain practices; cold storage monitoring was assessed by actual documentation of the temperature in Ice lined refrigerator and deep freezers at the time of visit and verification of the temperature monitoring chart. The availability of an alternative plan in the event of electrical failures was observed and recorded. To this end, direct observation of storage and distribution was carried out at facilities using an observation checklist designed by WHO.

4.8. Data quality assurance

To maintain the quality of the data, data collectors were trained for two days Five percent of questionnaires were pre-tested before the actual data collection in West Omo zone public health facilities. The Cronbatch alpha test was done to check consistency and obtained the value of 0.616 that signifies the consistency of the questionnaires. The principal investigator was checked the data collection forms at the end of each day and follow the completeness of data in all study sites. If any incomplete information it was correct next day at the similar facilities. Then the data were entered again and cross checked. For qualitative, KIs interview was undertaken in office setting on average 15-20 minutes. The audio recordings listen again and again. Next note was written in to data. Then the transcribed data from the KIs interviews were coded, and categorized under main thematic areas. Examined thematically and triangulate the qualitative findings.

4.9. Data entry, analysis and interpretation

The collected data from all public health facilities were checked, cleared, coded and processed. Then entered into Statistical Package for the Social Sciences (SPSS) software version 20 for data analysis. Descriptive statistics were done to describe data in frequency and percentage then the results were displayed using tables. In addition, target variables were analyzed to get the mean of the storage and distribution practices of CCPs by considering the variables employed to assess the storage and distribution practices of CCPs and then categorized as poor and good i.e. less than 80% was poor whereas greater than or equal to 80% was considered as good storage practice of CCPs. The chi-square test was done to identify the association between storage, distribution practice of CCPs with the sociodemographic variables in management of CCPs at a p-value of 0.05 significant levels. Moreover, the qualitative data from key informants (KIs) were collected through face-to- face interview was conducted with 12 key informants by principal investigator using LSAT until the saturation of ideas (36). Open-ended interview questions were conducted to get adequate information on studied variables. The interviews were prepared in English and translated in to target language (Amharic). During the interview, the note was taken and an audio recording was carried out for data transcription. In this regard, each KIs interview was taken on average 15-20 minutes. The audio recordings listen and note was written in to data. Transcribed data were coded, categorized and Summarized under main thematic areas and examined via thematically. Finally, the triangulation of the qualitative findings with quantitative results was carried out.

Operational definitions and definitions of terms

Cold Chain: is the system of transporting and storing CCPs at the recommended temperature range of $(+2^{\circ}C \text{ to } + 8 {}^{\circ}C \text{ for refrigerators})$ and $(-15^{\circ}C \text{ to } -25^{\circ}C \text{ for the freezer})$.

Cold chain pharmaceuticals (CCPs): These are pharmaceuticals that are managed in the cold chain.

Cold chain points: the service areas where CCPs are managed such as CCPs store,

dispensary, EPI services units and MCH unit from hospitals.

Cold chain distribution: is the delivery of CCPs in PHF at the right time in cold chain

Cold chain storage: storing of CCPs in PHFs in proper storage condition in the cold chain

Deep freezer: is the equipment used to store CCPs in negative temperatures $(-15^{\circ}C \text{ to } - 25^{\circ}C)$.

Refrigerator: is the equipment used to store cold chain pharmaceuticals in a temperature range of $(+2^{0}C \text{ to } + 8^{0}C)$

Public Health facilities: are the places that provide healthcare. This study included public health facilities such as hospitals and health centers.

Cold chain practice: Maintaining a network of cold chain equipment, personnel and procedures within the recommended temperature to safeguard their potency during storage, transport and delivery. This was measured by developing a practice scale i.e. good & poor practice by dividing the number of right practice to total practice questions (yes/total X 100%) into 2 parts which were categorized as poor practice- total score of <80% and good practice- total score of >=80% (1).

Ice-lined refrigerator: The type of refrigerator is specially designed for vaccine storage and is different from a normal top-opening refrigerator. It can keep vaccines safe with as little as 8 hours of electricity supply in 24hours, and comes in various sizes for use at different levels in the cold chain.

Vaccine Vial Monitor (VVM): A heat-sensitive indicator on the outside of a vaccine bottle that changes color when the vaccine has been exposed to excessive heat.

4.10. Ethical consideration

Ethical approval was obtained from the Institute of Health Science, Institutional Review Board (IRB), Jimma University on date 12/9/2012 E.C with reference number IRB000242/2012 to conduct the research in the selected study areas. Then the letter of cooperation was submitted to the Bench Sheko zone health department. The permission letter obtained from the Bench Sheko Zone health department was submitted to each woreda health office. Lastly, permission obtained from each woreda health office was submitted to health centers within respective woreda. During data collection, each respondent was informed about the purpose of the study, confidentiality of the data and written consent was taken from each respondent.

4.11. Dissemination plan of the study result

The final results of the study will be presented and its copies submitted to Jimma University Institute of Health Science, School of Pharmacy, and Bench-Sheko Zone Health Department. Finally, attempts will be made to publish the research in local or international journals reviewed by peer reviewers.

5. Results

5.1. Socio-demographic characteristics

The socio-demographic characteristics of the respondents were indicated in Table 1. From all selected 76 cold chain points (i.e. 72 from health centers and 4 from teaching hospital), a total of 76 cold chain points have participated in the study with an overall response rate was 92.6%. The majority, 60 (78.9%) were nurses, and about 56(73.7%) were diploma holders. More, 49 (64.5%) respondents had work experience between 1 to 5 years. However, the majority, 62 (81.6%) of professional who were involved in cold chain management were not trained and 57 (75%) were not supported by supportive supervision.

Table 1.Socio-demographic characteristics of the respondents in PHFs in SouthwesternEthiopia, 2021

Characteristics		Frequency (%)
Profession of cold chain managers	Pharmacy	16 (21.1)
Frotession of cold chain managers	Nurse	60(78.9)
Level of advantion	Diploma	56(73.7)
	Degree	20(26.3)
	Less than 1	8(10.5)
Work experience in years	1 to 5	49(64.5)
	6 to 10	19(25.0)
Completed cold chain management	Yes	14(18.4)
training last two years	No	62(81.6)
Supervision by the woreda health	Yes	19(25.0)
office	No	57(75.0)

5.2. Availability of cold chain equipment and infrastructure

The result in **table** 2 indicates the functional refrigerator was only 44(57.9%). The majority, 50(65.8%) of cold chain points did not have deep freezers, standard cold boxes, vaccine carriers, both cars, and motorcycles. Forty-nine (64.5%) of the cold chain points didn't have an adequate refrigerator for cold chain pharmaceuticals storage. Only 37(48.7%) cold chain points used thermometers and 26(34.2%) fridge tags as temperature monitoring devices. Some facilities used non-electricity sources in case of power failure; about 12 (15.8%) had an adequate generator. The majority, 60(79%), of do not have separate store, 56(73.7%) planed backup and 53(69.7%) also have no standard SOP or guideline.

Cold Chain Equipment	Yes (%)	No (%)
Availability of functional refrigerators	44(57.9)	32(42.1)
Functional Ice lined refrigerators(ILR)	26(34.2)	50(65.8)
Operational deep freezer	26(34.2)	50(65.8)
Standard cold boxes and vaccine carriers	26(34.2)	50(65.8)
Standard ice pack and foam pad	27(35.5)	49(64.5)
Calibrated functional min/max thermometer or fridge tag	37(48.7)	39(51.3)
Both Car and Motor bike used for transport	26(34.2)	50(65.8)
Separate store for cold chain pharmaceuticals storage	16(21.0)	60(79)
Maintained at recommended temperature (2°C-8°C) with	35(46.1)	41(53.9)
thermometers		
Sufficient capacity for storage of CCPs (at $+2^{\circ}C-8^{\circ}C$ and	27(35.5)	49(64.5)
-15°C to -25°C)		
Electricity power source in the facility	48(63.2)	28(36.8)
Non electricity(Solar, kerosene) power source in the	30(39.5)	46(60.5)
facility		
Power generator to maintain cold chain in case of electric	30(39.5)	46(60.5)
failure?		
Planned back-up storage unit(s) in the event of a power	20(26.3)	56(73.7)
failure		
Functional car/motorbike in the facilities to use in case of	31(40.8)	45(59.2)
refrigerator failure		
Use an up to date cold chain SOP /EPI guideline for	23(30.3)	53(69.7)
storage and distribution		
Overall total	30(39.47)	46(60.53)

Table 2. Availability of cold chain equipment and infrastructure in PHFs in Southwestern Ethiopia, 2021

5.3. Storage practice on cold chain pharmaceuticals

Of the 76 cold chain points involved in the study, less than half, 31(40.8%) of the facilities had maintained refrigerator temperature at 2–8°C, and 32(42.1%) of PHF monitor the temperature with a thermometer.

Only 25(32.9%) of PHF record twice-daily manual temperature monitoring charts by cold chain practitioners. Regarding freezer temperature maintained at -15 up to -25°C in PHF were 6(7.9%), and the presence of trays used for arrangements was 24(31.6%). Moreover, only 5(6.6%) of PHF have separate storerooms with 27(35.5%) of FEFO principles. Also, at the time of visit, only 4(5.3%) of facilities have a plan for preventive maintenance of CC equipment. Besides, about 45(59.2%) of the storage practice did not met the guideline, presence of CCPs on refrigerator door shelf 53(69.7%), in which about 58(76.3%) of PHFs lack a good arrangement of CCPs in refrigerators. Only 25% of good storage practice at PHFs fulfilled the WHO criteria.

No.	Parameter of storage condition	% of PHF	% of PHF
		WHO	WHO did not
		met criterion	met criterion
1	Refrigerator temperature maintained at 2–8°C	31(40.8)	45(59.2)
2	Monitor temp with thermometer or fridge tag	32(42.1)	44(57.9)
3	Temperature chart filled at 2-8°C during visit	31(40.8)	45(59.2)
4	Freezer temp. maintained at -15up to -25°C	6(7.9)	70(92.1)
5	presence of trays used for arrangements	24(31.6)	52(68.4)
6	Document temp. on the appropriate log	27(35.5)	49(64.5)
7	Call appropriate personnel temp out of range	6(7.9)	70(92.1)
8	Separate store room for CCPs storage	5(6.6)	71(93.4)
9	Store CCPs on the FEFO principle	27(35.5)	49(64.5)
10	Record temp. twice daily	25(32.9)	51(67.1)
11	Other product store with CCPs(specimens, food	19(25.0)	57(75.0)
	&drink)		
12	Plan for preventive maintenance CC equipment	4(5.3)	72(94.7)
13	Availability of spares and consumables for	3(3.9)	73(96.1)
	maintenance		
14	CCP found in domestic refrigerator	5(6.6)	71(93.4)
15	Storage practice not in contrary to guideline	31(40.8)	45(59.2)
16	No CCPs on refrigerator door shelf	23(30.3)	53(69.7)
17	Freezer temp found below -25°C	6(7.9)	70(92.1)
18	Expired CCPs placed separately & label	28(36.8)	48(63.2)
19	Good arrangement of CCPs in refrigerators	18(23.7)	58(76.3)
20	CCPs stock record correctly & timely updated	18(23.7)	58(76.3)
21	Enough CCPs storage space	10(13.2)	66(86.8)
22	Storage equipment are fully functional	31(40.8)	45(59.2)
23	Trained staff in CCM in health facility	14(18.4)	62(81.6)
24	SOPs are available to ensure proper CCPs of	23(30.3)	53(69.7)
	storage		
	Overall total	19(25)	57(75)

Table 3. Parameter of storage condition with a percentage of WHO met criterion at study PHFs in Southwestern Ethiopia, 2021

5.4. Distribution practice of cold chain pharmaceuticals

Among 76 cold chain points included in the study, only 27(35.5%) of PHFs monitor the temperature with a thermometer, and about 24(31.6%) of PHFs document temperature on an appropriate log. Regarding standard vaccine carrier, a program for distribution, rotate CCPs on the FEFO principle and check the expiry dates of CCPs during distribution was 30(39.5%), 50(65.8%), 36(47.4%), and 33(43.4%) respectively. None of the facilities did have a special vehicle for transportation and distribution guidelines. All PHFs, 76(100%) had a distribution schedule monthly, and 54(71.1%) of PHFs delivery and distribution within recommended schedule. Only 27.63% good distribution practice of cold chain pharmaceuticals at PHFs fulfilled the USAID delivery guide (LIAT) criteria.

No.	Distribution practice	Yes (%)	No (%)
1	Monitor temperature continually with max-min	27(35.5)	49(64.5)
	thermometer		
2	Document temperature on appropriate log	24(31.6)	52(68.4)
3	Types of transportation used (car, motorcycle)	33(43.4)	43(56.6)
4	Have standard vaccine carrier for transportation	30(39.5)	46(60.5)
5	Use validated cold box with thermometers & ice pack	25(32.9)	51(67.1)
6	Program for distribution of CCPs	50(65.8)	26(34.2)
7	Rotate CCPs on the FEFO principle	36(47.4)	40(52.6)
8	Correctly record temperatures during transportation	1(1.3)	75(98.7)
9	Plan for preventive maintenance of CC equipment	1(1.3)	75(98.7)
10	Check the expiry dates of CCPs during distribution	33(43.4)	43(56.6)
11	Special vehicle for transportation of cold chain	0	76(100)
12	Appropriate transportation used during distribution	4(5.3)	72(94.7)
13	Temperature monitoring was done during	1(1.3)	75(98.7)
	transportation		
14	Temp. monitoring between 2-8°C during	1(1.3)	75(98.7)
	transportation		
15	Distribution guide line available in HF	0	76(100)
16	Documentation done during transportation	15(19.7)	61(80.3)
17	Distribution schedule available in monthly	76(100)	0
18	Delivery and distribution within recommended	54(71.1)	22(28.9)
	schedule		
19	SOPs available for proper transport conditions	1(1.3)	75(98.7)
20	Supervision done by health department	19(25)	57(75.0)
21	Insulated coolers available for distribution	5(6.6)	71(93.4)
	Overall total	21(27.63)	55(72.37)

Table 4. Distribution practice of CCPs at study public health facilities in SouthwesternEthiopia, 2021

5.5. Factors associated with storage practice

The poor storage practice of CCPs was significantly associated with different variables as displayed in **table 5**. The chi-square statistics revealed that a statistically significant relationship between storage and variable included in table 6, such as work experience, X^2 (2, N=76)=26.65, p=0.009, training $X^2(1, N=76)=10.72$, p=0.005, and supervision $X^2(1, N=76)=3.82$, p=0.014.

			Storage		
Variable			Good (%)	Poor (%)	P-value
Drofessionals	Pharmacy	16	2(66.7)	14(19.2)	
FIOLESSIONAIS	Nurse	60	1(33.3)	59(80.8)	0.110
Loyal of advantion	Diploma	56	1(33.3)	55(75.3)	
Level of education	Degree	20	2(66.7)	18(24.7)	0.168
	Less than 1	8	0(0.0)	8(11.0)	*
Work experience	1 to 5	49	0(0.0)	49(67.1)	0.009
	6 to 10	19	3(100)	16(21.9)	
Training	No	62	0(0.0)	62(84.9)	· · · · · · *
ITaning	Yes	14	3(100)	11(15.1)	0.005
a	No	57	0(0.0)	57(78.1)	· · · · *
Supervision	Yes	19	3(100)	16(21.9)	0.014

Table 5. The X^2 - association between the storage practices with variables on CCPs at PHFs in Southwestern Ethiopia, 2021

* Significant at a p-value of 0.05

5.6. Factors associated with distribution practice

The chi-square statistics indicated that the association between the distribution with selected variables such as the level of education, $X^2(1, N=76) =5.034$, p=0.024), work experience $X^2(2, N=76) =11.902$, p=0.003), training $X^2(1, N=76) =6.427$, p=0.000, and supervision $X^2(1, N=76) =28.8$, p=0.000 was statistically significant association as shown in **table 6**.

Table 6. The X^2 - association between distribution practice with variables on CCPs at PHFs in Southwestern Ethiopia, 2021

			distril		
Variable			Good (%)	Poor (%)	P-value
Professionals	Pharmacy	16	10(27)	6(15.4)	
	Nurse	60	27(73)	33(84.6)	0.168
	Diploma	56	23(63.2)	23(79.3)	
Level of education	Degree	20	14(37.8)	6(20.7)	0.024*
	Less than 1	8	5(13.5)	3(7.7)	
Work experience	1 to 5	49	17(46)	32(82.05)	
Ĩ	6 to 10	19	15(40.5)	4(10.25)	0.003^{*}
Training	No	62	26(70.28)	36(58)	
	Yes	14	11(29.72)	26(42)	0.014*
Supervision	No	57	20(54.1)	37(94.9)	
	Yes	19	17(45.9)	2(5.1)	0.000^{*}

* Significant at a p-value of 0.05

5.7. Qualitative results

The challenges of cold chain pharmaceutical storage and distribution lead to poor practices were identified through face-to-face KIs interview. The key informants were selected based on their service experience and position. The results were thematically analyzed by categorizing the data based on the function of the data described and summarized under the following themes.

Personnel related

The challenge identified by the majority of KIs in health centers was a shortage of professionals. The storemen complained that due to the lack of pharmacy professionals at the facility they assigned nurses to manage pharmaceuticals. The study also explored the shortage of pharmacy practitioners on cold chain management related to storage and distribution in CCPs.

Regarding this information had to say: ... "I am responsible for various tasks in my facility. A person assigned to work in the facilities, for example, may also be responsible for other pharmacy tasks. Currently, in my facility, I am," one of the storemen clarified the problem. (Age 36, 7 years' work experience and storemen).

Another KI stated that:

The key reasons mentioned by the interviewees were high staff turnover, a shortage of pharmacy professionals, and a limited number of pharmacy professionals made by government higher education institutions *explained the problem.as:* "...Since the majority of pharmacy professionals in health centers are dissatisfied with their current profession." (Age 42, 12 years' work experience and pharmacy head)

Infrastructure related challenges

Most of the KIs raised infrastructure-related challenges; in this sense, most KIs from the HCs complained about a shortage of electric power, lack of equipment and transportation. Some of the causes of the problem were mentioned by the main informants. This problem is explained by one of the KIs as follows:

"... The problem is even worse among workers at rural health facilities, shortage of infrastructure, for example, power supply, cold chain equipment, and transportation." (Age 49, 17 years' work experience and EPI focal person)

In addition to the problem of the infrastructure, other KIs also revealed that:

"... Health centers face a lack of alternative power supply and temperature monitoring devices, power interruption and breakdown of power sources were the main challenges." (Age 39, 9 years' work experience and storemen)

This problem was identified by other KIs as follows: "… An unreliable power supply such as electricity and lack of alternative power source during power breakdown appears to be the major challenges in maintaining the recommended temperature range for the proper cold chain storage" (Age 36, 7 years' work experience and storemen)

Another KI also explained the problem as:

"... Shortage of functional cold chain equipment and inadequate health workers personnel at some public health facilities in maintaining cold chain storage and distribution practice" (Age 42, 11 years' work experience and pharmacy head). Similarly, another key informant said; "... the lack of cold chain equipment and spare parts and lack of equipment maintenance were major obstacles in order to effectively control the cold chain pharmaceutical storage practice (Age 42, 10 years' work experience and storeman).

Managerial related challenges

Poor management and feedback that is not positive. In addition, the facilities had insufficient administrative resources to efficiently maintain their storage and distribution of CCPs.

Regarding this problem described as follows;

"... The majority of the study facilities' top managers don't regard CCPs as a pharmacy professional responsibility in the facility. As a result, the professionals lack the incentive to properly handle CCM and ineffective management and unfavorable reviews. In addition, the facilities lack the administrative support needed to keep their information systems up to date. The recording system is not viewed as a straightforward pharmacy facility by the majority of the study facilities' top managers. As a result, the staff suffers from lack of motivation to manage storage and distribution data properly, and the majority of professionals do not document the temperature of a cold chain". (Age 38, 11 years' work experience and pharmacy head)

Most KIs raised that there was a lack of supervision from top management and training as contributing factor for poor practices. In this regard one of the KIs explains this as:

"... Inadequate supportive supervision from the top management, lack of training and SOP, shortage of transportation. In general unavailability of infrastructure leads to poor storage and distribution practice" (Age 34, 6 years' work experience and EPI focal person)

Knowledge related

Lack of Knowledge is important contributing factor for poor practices of cold chain management. In addition to the difficult of the poor storage and distribution practice, KIs also complained about the lack of training in cold chain pharmaceutical storage and distribution practices. This problem was stated by one of the KIs as follows:

"... There were limited regularities of training "I have been working here, I haven't got chance to train storage and distribution of cold chain pharmaceuticals and supervised" (Age 38, 9 years' work experience and storemen)

Another KI indicated that:

"... One of the challenges affecting pharmacy activities is lack of training and supervision to health professionals. This has contributed to poor storage and distribution practices in public health facilities" (Age 36, 7 years' experience and pharmacy head)

6. Discussion

This study revealed that to identify gaps in training, supervision, practice of the cold chain pharmaceuticals, availability of equipment and infrastructure at public health facilities in the Bench-Sheko Zone, Southwestern Ethiopia. The present study indicated that only 18.4% of professional trained and 25% were supported by supervision. The results were lower than study conducted in Ethiopia, Nekemte 59.6%, Gurage Zone, 57.6%, Southern Nigeria, 73.9% (21,23,37). The difference could be lack of training, & inadequate supervision. The main challenge explored by the study. One of the key informants stated that: "… One of the challenges affecting pharmacy activities is lack of training and supervision to health professionals. This has contributed to poor storage and distribution practices in public health facilities" (Age 36, 7 years' experience and pharmacy head).

Providing infrastructure& cold chain equipment are critical in cold chain management. Majority cold chain equipments such as functional refrigerator, DFs, standard cold boxes, vaccine carriers, thermometer, planed backup, standard SOP were not uniformly available throughout health facilities. This finding is different to those reported northwest Cameroon, India, Philippines and Southern Nigeria (11,31,33,37). The possible reason might be due to low availability of equipment, infrastructure, and lack of supervision. The availability of cold chain equipment was critical problem in proper cold chain management. One of key informant identified: "… *The problem is even worse among workers at rural health facilities, shortage of infrastructure, for example, power supply, cold chain equipment, and transportation.*" (*Age 49, 17 years' work experience and EPI focal person*). Another KI also explained the problem as:

"... Shortage of functional cold chain equipment and inadequate health workers personnel at some public health facilities in maintaining cold chain storage and distribution practice" (Age 42, 11 years' work experience and pharmacy head)

Storage practice at public health facilities is fundamental for good management of CCPs. This study finding was lower than the study results from Damoh district of Madhya Pradesh about 73.9%, Northwestern Nigeria, in Giwa, 51.3%, and Nigeria, Oyo State 66.1% had good CCM practices (26–28). Similarly, the finding from Southeast Ethiopia, Bale Zone 40%, and Amhara region, in East Gojam zone 58.3% and Nigeria, Edo State 36% public health facilities was higher than the present study storage practice of CCM (8,20,24). The discrepancy in storage practices from different studies with the current study might be due to

low work experience of health professionals particularly working in CCM, lack of supervision on CCM how it was functioning, absence of SOP, failure to follow FEFO principle, lack of training, absence of equipment such as (refrigerator, thermometer), and inadequate infrastructure like (electricity, separate store room and backup power). The consequence of poor storage practices of cold chain pharmaceuticals may lead to loss of potency, increase wastage of products, clients can lose confidence and expiry that increased disease burden, and medical costs to patients (12). The underlying challenges were identified by qualitative methods accordingly, shortage of professionals, lack of electric power, equipment, alternative power supply and temperature monitoring devices, supportive supervision, SOP, and training. The majority of cold chain equipment, such as the functional refrigerator, deep freezers, standard cold box, vaccine carriers, were low available throughout the health facility. This study's findings are lower than those reported in the northwest region of Cameroon, and Southern Nigeria (15,37). This difference might be due to lack of cold chain equipment, poor knowledge and inconsistency in the power supply.

However, fluctuated power supply and shortage of resources like equipment, professionals knowledge are the challenges of cold chain storage practices. Those health facilities using electricity as their primary power source mostly used but the major problem of the power source was an inconsistency in the power supply that interrupts the cold chain storage practice. On other parts, the availability of essential spare parts and conducting cold room maintenance were very low. This problem was identified by one of the main informants as follows:

"... An unreliable power supply such as electricity and lack of alternative power source during power breakdown appears to be the major challenges in maintaining the recommended temperature range for the proper cold chain storage" (Age 36, 7 years' work experience and storemen). Likewise, another key informant said; "... the lack of cold chain equipment and spare parts and lack of equipment maintenance were major obstacles in order to effectively control the cold chain pharmaceutical storage practice (Age 42, 10 years' work experience and storeman).similarly reported the same challenges of CCM.

All health care professionals working in PHFs should receive mandatory cold chain management training before they initiate clinical practice to ensure delivery of safe and effective CCPs (38). The poor or low distribution practice may compromise the potency of the CCPs and the quality of the services. The study finding was in line with the study

conducted in Ghana, only 27% effective cold chain distribution practice (18). This could be low transportation, equipment and poor knowledge. The current study was lower than study conducted in, East Gojam zone 58.3% (20). The variation might be due to differences in sample size, inadequate training of CCM workers, lack of supportive supervision, lack of temperature monitoring device (thermometer), inappropriate transportation, shortage of standard vaccine carrier and ice pack. Mainly, transportation was a major contributor to exposure to both heat and freeze. Besides, the use of outdated and uncertified cold chain equipment and gaps in healthcare worker knowledge, and practices were important contributors to unintended exposures and poor practice (19). The consequence of poor distribution practices of cold chain pharmaceuticals may results compromise potency, reduce quality of service; increase overall cost and high level of wastage (7,29). Particularly USAID delivers project claimed that effective supervision and on-the-job training for supply chain management at the health facility could improve distribution practices of CCPs (39).

Most KIs raised that there was a lack of supervision from top management and training as contributing factor for poor practices. In this regard one of the KIs explains this as:

"... Inadequate supportive supervision from the top management, lack of training and SOP, shortage of transportation. In general unavailability of infrastructure leads to poor storage and distribution practice" (Age 34, 6 years' work experience and EPI focal person)

In addition to the difficult of the poor storage and distribution practice, KIs also complained about the lack of training in cold chain pharmaceutical storage and distribution practices. This problem was stated by one of the KIs as follows:

"... There were limited regularities of training "I have been working here, I haven't got chance to train storage and distribution of cold chain pharmaceuticals and supervised" (Age 38, 9 years' work experience and storemen). Another KI indicated that: "... One of the challenges affecting pharmacy activities is lack of training and supervision to health professionals. This has contributed to poor storage and distribution practices in public health facilities" (Age 36, 7 years' experience and pharmacy head.

In addition, work experience was statistically significant association with the storage practice X^2 (2 N=76) =26.65, p=0.009. This study in line with study reported from Bahirdar, health workers with more than two years of work experience have 5 times more likely to have proper practice on cold chain management compared to their counterpart with 95%. Also in

current study training $X^2(1 \text{ N}=76) = 10.72$, p=0.005, and supervision $X^2(1 \text{ N}=76) = 3.82$, p=0.014 was statistically significant association with the storage practice (34).

Work experience $X^2(2, N=76) = 11.902$, p=0.003), was statistically significant association with the distribution practice. This study in line with study reported from Bahirdar, health workers with more than two years of work experience have 5 times more likely to have proper cold chain practice. Similarly, in present study the level of education, $X^2(1, N=76)$ =5.034, p=0.024), training $X^2(1, N=76) = 6.427$, p=0.000, and supervision $X^2(1, N=76) = 28.8$, p=0.000 was statistically significant association with the practice of health workers.

7. Conclusion and Recommendation

7.1. Conclusion

The principle for cold chain management is keeping up of the products within recommended practice to manage strong and quality services to clients. This study showed that there was a gap in the cold chain pharmaceuticals practices at PHFs. Such as lack of training and supervision, absence of infrastructure and equipment at public health centers appears to be the key challenge in continuing the good storage and distribution practice. Adherence to good practices like unreliable power supply, maintenance of cold chain equipment, infrastructure, equipment, supervision correctly required to improve cold chain practices. Thus, the public health facilities have to make sure of the availability of cold chain equipment infrastructures like power sources, transportation, and supervision. Provide access to the power supply and minimize power interruption at public health facilities by having a minimum of one replacement as the source of power through government and stakeholders' participation. The finding indicated that there was a poor storage and distribution practice of CCPs in this study area. Hence, there is a need of improving the CCPs practices through training, availability of SOPs and supervision, etc. The major challenges that influence the storage and distribution practice appropriately were identified such as shortage of professionals, lack of electric power, scarcity of equipment and transportation, inadequate alternative power supply and temperature monitoring devices, lack supportive supervision, absence of SOP and lack of training inability to implement cold chain practice. In addition, this study provided evidence for public health planners, policymakers, and health professionals in ensuring the quality and safety of products are not compromised during the storage and distribution of cold chain pharmaceuticals.

7.2. Recommendation

Thus, the following practical recommendations must be implemented at all concerned levels to improve CCPs storage and distribution practices.

- All health facilities, particularly those serving on CCM, should have proper and effective storage and distribution practices, as well as on-the-job training and regular supportive supervision provided by Zonal health department and woreda health office.
- Cold chain program coordinators at the zonal and woreda levels should provide ongoing training and support for CCPs, as well as assign experienced health professionals (pharmacy) to close the practice gap.
- SOPs, cold chain equipment, and a power supply should be accessible at PHFs, according to the Federal Ministry of Health (FMOH).
- Further research should be done at regional and national level using both qualitative and quantitative methods to detect gaps and recommend possible solutions.

7.3. Strength and limitation of the study

The strength of the study

- Tried to find the actual data by using the direct observation checklist.
- Have included all public health facilities to know the existing storage and distribution practice of CCPs.
- Experienced and Skilled professional were employed for data collection to decrease information bias.

The limitation of the study

• Absence of comparative studies for comparing and differentiating the results.

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Annexes

1. Sampling technique



Jimma University

Institute of Health

School of Pharmacy

2. Information sheet and consent form

Dear respondent, My Name is Fikere Alemayehu My colleague is ______. I came from Jimma University. I am doing research "Cold chain pharmaceuticals storage and distribution practices in public health facilities in Bench-Sheko Zone, Southwestern Ethiopia" for the partial fulfillment of MSc program of pharmaceutical supply chain management (PSCM) in Jimma University. I would like to ask you some questions about the storage and distribution practice of cold chain pharmaceuticals in your facility by using indicators LIAT, LSAT assessment tools and WHO check-list.

The purpose of visiting this health facility is to assess the storage and distribution practice of cold chain pharmaceuticals in this facility, and to collect information on the storage and distribution practice of cold chain pharmaceuticals and its challenges in the facilities. The result of this study is expected to identify the major gaps in the the storage and distribution practice of cold chain pharmaceuticals and will put possible solutions to ensure the availability and proper use of cold chain pharmaceuticals. After I get your consent, my colleague and I will collect the data confidentially. Moreover, I would like to visit the storage areas to check practices today, and observe the general storage conditions. Since you involve in this study, I will take 20– 30 minutes of your time. But this study doesn't have any additional discomfort. By participating in this study, you may not get any compensation or benefit right now. But the results of the assessment will provide information for developing recommendations and planning improvements in the storage and distribution practice.

This assessment is not a supervisory visit, and the practice of individual staff members is not being evaluated. We are not going to take any personal identifiers. The collected data will be analysed in aggregate without making any personal manipulation. If you feel any discomfort or harm, you can withdraw from the study at any time. In addition to this, you are not obliged to answer each question. You have the full right to refuse your participation in the study. But I encourage your full participation as the answers you give on this form and your participation are very important to this study. Would you be willing to participate in this study?

Interview accepted: Yes \Box No \Box . If the interviewee responds "Yes", please sign and proceed.

If you have any questions concerning the study, please call for principal investigator Fikere Alemayehu: 09-10-06-89-96 (MSc Candidate in PSCM), JU, institute of health, school of pharmacy.

Signature of respondent Signature of the interviewer

Date: _____ (Day/month/year)

Thanks very much for your participation

Jimma University Institute of Health School of Pharmacy

3. Consent form

I am informed fully in the language I understand about the aim of the above-mentioned research. I understood the purpose of the study entitled "on cold chain pharmaceuticals storage and distribution practices in public health facilities in Bench-Sheko Zone, Southwestern Ethiopia". I have been informed about this study which involves collecting health professional's sample. I have also read the information sheet or it has been read to me. In addition, I have been told all the information collected throughout the research process will be kept confidential. I understood my current and future medical services will not be affected if I refused to participate or withdraw from the study. I _______, after being fully informed about the detail of this study, hereby gave my consent to participate in this study and approve my agreement with signature.

Health professional's name	Signature	Date
Investigator name	Signature	_Date

4. Data collection tool

a. Data collection tool for quantitative

Code No.....

Name of Healthcare Facility.....

General direction; Encircle your choice

Note: some questions may have more than one choice, so encircle all your choices

Questionnaires, English version

Part I: Questionnaires to Socio-demographic characteristics

1. Cold chain store Professional person-in-charge of the facility.					
a) Pharmacy	b) Nurse	c) Health of	fficer	d) Others (mention)	
2. Level of education a) Below diploma b) Diploma c) Degree d) Above degree					
3. Work experience (in years) on CCPs/vaccine storage and distribution					
a) Less than 1	b) 1 to 5	c) 6 to 10	d) Gr	reater than 10	
4. Do you have any pre-training in cold chain management before being employed?					
A) Yes	B) No				
5. Have you attended any in-service training on cold chain management?					
A) Yes	B) No				
6. Have you ever completed cold chain management training in the last two years?					
A) Yes	B) No				
7. What type of training do you train in CCM?					
A) Cold chain storage and distribution of CCPs/vaccine)		B) Cold chain equipment			
maintenance					
C) Both				D) others (specify)	
8. Supervision is done by woreda health office?					
A. Yes	B. No				
9. How many times in a year? Specify					

Thank you for your cooperation!

Part III. Check list to assess cold chain equipment/ infrastructures, cold chain

pharmaceuticals, storage and distribution practice

Tick (\checkmark) for Yes and (\bigstar) for No under Yes & No according to the respective questions. (Verify by physical observation)

A. availability of cold Chain equipment/ infrastructures			No	
A01- Does your facility has functional refrigerators?				
A01- Does your facility has functional Ice Lined Refrigerators (ILR)				
A02-Does your facility have operational de	eep freezer?			
A03- Do have standard cold boxes and vaccine carriers are available?				
A03.1-Do have standard Ice pack and foam pad are available?				
A03- Do you have (refrigerators/freezers) equipped with a calibrated functional				
min/max thermometer or fridge tag?				
A04-Both Car and Motor bike used for transport?				
A05- Does your facility has a separate stor	e for cold chain p cold chain			
pharmaceuticals storage?				
If No, reason	If No, reason			
A06- Is it operational and maintained at recommended temperature (2 ^o C -8 ^o C)?				
If No, reason				
A07- Does it has sufficient permanent capacity for storage of cold chain				
pharmaceuticals (at $+2^{\circ}$ C to 8° C and -15° C to -25° C)				
A.08-What is the main power source in	Electricity			
the facility Non-electricity(Solar, kerosene)				
A08.1-Does your facility has power generator to maintain cold chain in case of				
electric failure?				
Other alternative, specify				
A09- Is there planned back-up storage unit(s) in the event of a power failure				
or other unforeseen event?				
A10-Availability of functional car/motorbike in the facilities to use in case of				
refrigerator failure?				
A11-Do you use an up to date cold chain SOP /EPI guideline (reviewed within				
the last two years) for storage and distribution practice of CCPs/ vaccines?				
If No, ,reason				
B. Storage practice related factors				

B01-Is refrigerator temperature maintained at (2–8°C)? (ask to see)			
B02-Do you monitor temperature continually with a maximum– minimum			
thermometer/fridge tag?			
B02.1. Do you have source of power in health institution			
Specify source of power			
B03-Do you have temperature chart on refrigerators (ask to see)			
B03.1. Temperature chart filled between (2–8°C) during visit			
B04-Is freezer temperature maintained at below of -25°C (ask to see)			
B05-Do you record and monitor the minimum, maximum and actual			
temperatures in the refrigerator at least once each working day?			
If No, reason			
B06- Are temperature records readily accessible and retained until the next			
audit?			
B06.1-Presence of trays which are used for arrangements			
B07-Do you document refrigerator and freezer temperatures on the			
appropriate log?			
B08-Do you follow the directions on the temperature log to call appropriate			
personnel if the temperature in a storage unit goes out of range?			
B09-Does your facility have a separate store room for cold chain pharmaceuticals			
storage?			
B09.1-Do you store CCPs in separate, self-contained units that refrigerate or			
freeze only?			
B10-Do you store CCPs on the "first to expire, first out" FEFO principle ?			
If No, reason			
B11-Do you record temperatures twice daily?			
B12- Have you not stored anything other than cold chain pharmaceuticals in the			
refrigerator (including specimens, food &drink)? (ask to see)			
B12.1-Do you have a plan for replacement of cold chain equipments that have			
served long period of time (>10 years)?			
B12.2-Do you have a plan for preventive maintenance of cold chain			
equipments?			
B12.3-Do you carry out an emergency repair of cold chain equipment in timely			
manner?			

B12.4-Do adequate supplies of spares and consumables are available for			
equipment maintenance?			
B13- Cold chain pharmaceuticals found in domestic refrigerator			
B13.1–storage practice are not in contrary to guideline			
B13.2–No storage of cold chain pharmaceuticals on refrigerator door shelves			
B13. 3- Freeze found with temperature below -25°C			
B13.4 -Do you clearly label close to expiry CCPs/ vaccines? (ask to see)			
B13.4.1. Expired CCPs placed separately(ask to see)			
B13.5-Good arrangement of cold chain pharmaceuticals in refrigerators	B13.5-Good arrangement of cold chain pharmaceuticals in refrigerators		
B13.6 - Do you fill CCPs/vaccine stock record books correctly and timely			
(update)? (ask to see)			
B14-Special storage area available for CCPs in the facility			
B15-Is there enough CCPs storage space			
B16-Storage equipment are fully functional			
B17- There is different storage equipment for different kinds of CCPs			
B18-Is there trained staff in CCM in health facility?			
B19- SOPs are available to ensure proper CCPs of storage			
B20-Is there power interruption during storage?			
B20.1- In case of power failure, what is alternative used, specify			
B21.1- How many times in a year specify			
C. Distribution practice related factors			
C01- Do you monitor temperature continually with a maximum–minimum			
CO2 Do you document CCPs temperatures on the appropriate log?			
C02 Do you have means of transportation			
C03.1- What kind of transportation (specify)			
C04- Do you have standard vaccine carrier for transportation			
C04.1- Do you use validated cold boxes with thermometers and ice packs?			
C04.2-Do you have a program for distribution of CCPs/vaccine from issuing store			
to each receiving store?			
C05 Do you rotate CCPs on the "first to expire, first out" FEFO principle?			
C06- Do you record temperatures during transportation			
C07- Do you have a plan for preventive maintenance of cold chain equipments?			
C08 Do you check the expiry dates of CCPs during distribution			

C09 Supervision done by health department				
C10- Is there a special vehicle for transportation of cold chain items?				
C11- Appropriate mode of transportation is used				
C12- Is there temperature monitoring system during transportation				
C13- Temperature readings remain between 2-8°C during transportation				
C14- Is there distribution guideline available in health facility?				
C15- Documentation done during transportation				
C16- Distribution schedule time table is	Once monthly			
available	Twice monthly			
	No			
C17- Delivery and distribution is done within recommended schedule				
C18- SOPs are available to ensure proper transport conditions				
C19-Is there an insulated container (Coolers) to meet demand for distribution?				

5. Consent form for qualitative tool

First of all, we want to thank you for giving your time to undergo this conversation. Having said this we will need you enough information about the study that we are going to do and please listen with full attention. Finally, if there is any question you can ask and get information.

My name is ------I am conducting a study on cold chain pharmaceuticals storage and distribution practices in public health facilities in Bench-Sheko Zone, Southwestern Ethiopia in order to fulfill the University requirement set for awarding of a Master Degree in pharmaceutical supply chain management. The study is purely for academic purposes and thus not affects you in any case. The interview will take 15-20 minutes and conducted individually. All your responses will be kept strictly confidential by using only code numbers and not be shared with anyone. No one will have access to get data except the principal investigator. I hope you will agree to answer the questions. So, react honestly and timely response is vital for the successfulness of the study. Therefore, I kindly ask you to respond very carefully to each item of the request.

Would you be willing to participate? Yes (proceed) No (stop interview here)

Contact Address

Please do not hesitate to contact me if you have any questions, and I am available as per your Convenience at (Mobile: 09-10-06-89-96 or email: <u>alemayehufikere@gmail.com</u>)

Thank you in advance for scarifying your precious time!

6. Qualitative data collection tool

Key informants interview guide in-depth interview at a public health facility for store managers and pharmacy heads, and EPI focal person.Responsibilities..... 1. What are the challenges faced in storage practices of CCPs in your health facility? Please list..... 2. What are the challenges faced in the distribution practices of CCPs in your health facility? Please list 3. In which area do you think professionals face problems during distribution? Why? 4. In your own opinion, what are some barriers if any, that you encountered inefficient cold chain management? Please list. 5. What are other problems that make storage and distribution challenges in your health facility? 6. How did you overcome the barriers? 7. What do you finally recommend to the woreda health department, Regional health bureau, FMOH/ on storage and distribution of CCPs?

Thank you for your cooperation!