

ORIGINAL RESEARCH

Cold Chain Maintenance and Vaccine Stock Management Practices at Public Health Centers Providing Child Immunization Services in Jimma Zone, Oromia Regional State, Ethiopia: Multi-Centered, Mixed Method Approach

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Department of Pharmaceutics and Social Pharmacy, School of Pharmacy, College of Medicine and Health Sciences, Mizan-Tepi University, Mizan-Aman, Ethiopia Background: Cold chain maintenance is the spine of an immunization program.

Objective: To examine the status of cold chain maintenance and evaluate knowledge of cold chain handlers and practices of vaccine management at public health centers providing immunization services in Jimma zone.

Methods: An institutional-based cross-sectional study supplemented with a qualitative method was conducted in 41 randomly selected health centers providing immunization service in districts of Jimma zone from October 31 to November 30, 2019. Pre-tested self-administered questionnaires and observation checklists developed from an effective vaccine management assessment tool (EVMAT) were used to collect quantitative data. Key informants were selected using the purposive sampling technique and an in-depth interview was conducted. Quantifiable data were analyzed using SPSS version 20 and chi-square was used to test the presence of association (p-value <0.05). Qualitative data were analyzed by thematic analysis and triangulated with quantitative findings.

Results: All public health centers had at least functional ice-lined refrigerators while 28 (68.3%) public health centers had functional deep freezers. Of the cold chain handlers, 120 (82.9%) had fair knowledge. Vaccine storage was appropriate per the World Health Organization's vaccine storage code in ice-lined refrigerators in 11 (24.4%) public health centers. Cold chain handlers' years of service, types of training, availability of funds for cold chain maintenance, and availability of cold chain equipment at public health centers showed the presence of significant association with vaccine cold chain management practice.

Conclusion: The majority of cold chain handlers showed inadequate knowledge while a significant number showed poor practice of preserving the vaccines' cold chain. Cold chain maintenance was not adequate in public health centers, necessitating attentive efforts of providing proper management of vaccine cold chains at immunization delivery points.

Keywords: cold chain management, maintenance, vaccine, public health centers, Jimma, southwest Ethiopia

Introduction

Immunization is widely acknowledged as one of the most cost-effective community health interventions available today. ^{1–3} The World Bank estimated that the child-hood vaccination program was averting more than 2.5 million deaths every year. ⁴

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Despite this fact, there are 30 million children who are not routinely immunized every year. Vaccine-preventable diseases (VPDs), namely, measles, pertussis, *Haemophilus influenzae* type B (HIB), and tetanus, account for 25% of the 10 million deaths occurring annually for children under five years of age and 29% of all childhood mortality worldwide. Most of those deaths occur in developing countries, especially in Africa.

In Ethiopia, about 470,000 children die per year; here, a child is 30 times more likely to die by his or her fifth birthday than a child found in Western Europe. 8 Over 85% of child mortality is attributable to the newborn period resulting from pneumonia, and diarrhea which is vaccine-preventable. As witnessed in the sustainable development goal, reduction in child mortality has received the proper attention worldwide. Children under one year of age are the primary targets for the EPI vaccines (BCG, measles, DPT-HepB-Hib (pentavalent vaccine), OPV, and TT vaccine in Ethiopia. 11

Delivery of potent vaccines to children through a properly maintained cold chain system and achieving high vaccine coverage need to be monitored to reduce child death. Proper cold chain management is considered as one indicator of an effective immunization program. Vaccines are delicate biological molecules that irreversibly lose potency and efficiency when exposed to temperatures outside the recommended ranges. The quality of the vaccine is maintained using a cold chain that meets specific temperature requirements. WHO recommends keeping vaccines in the appropriate vaccine refrigeration equipment using a temperature monitoring device to ensure temperatures remain between +2°C and +8°C and transporting vaccines to immunization sessions in a vaccine carrier through properly prepared coolant packs at health facility level. 19,20

Cold chain maintenance and temperature monitoring is still a major challenge in developing countries, where only around 56% of health institutions adhered to twice daily registration of the temperature records.²¹ Dedicated vaccine refrigerators, electronic refrigerator temperature loggers, and vaccine vial monitors (VVM) are essential elements for ensuring the viability of vaccines.²² Vaccines such as OPV, measles, varicella, and oral typhoid are unstable to heat, while other vaccines such as DPT, HepA, HepB, and TT are sensitive to freezing.^{23–26}

Vaccine cold chain storage errors cost fortunes in wasted vaccine, revaccination, and specialized transportation. ^{27,28} In 2011, 50% of GAVI (Global Alliance for Vaccines and Immunization) eligible countries reported a vaccine wastage

rate exceeded what is recommended by the WHO and 2.8 million vaccine doses lost in 5 countries of the world resulting from cold chain failures.²⁹

Considering vaccines require more complex handling and storage requirements owing to increased temperature sensitivity and complicated vaccination schedules, effective management of the vaccine cold chain system at all levels is one of the most crucial criteria for sustaining vaccine potency.³⁰ Availability of cold chain equipment, cold chain handlers' knowledge, training, supervision, and cold chain management practice are critical determinants of the sustainability and effectiveness of immunization programs.^{21,31} Inadequate knowledge of vaccine cold chain handlers and improper practice of cold chain maintenance is one of the common challenges among public health centers, especially in remote areas. 32-35 Adequate training and supportive supervision improve healthcare workers' knowledge and cold chain management practices. Good practices maintain proper vaccine storage and handling that ensure the full benefit of immunization.³⁶

An effective cold chain relies on reliable cold chain equipment (CCEs) and temperature monitoring devices. These CCEs include electrical equipment like cold room/walk-in coolers and freezer room/walk-in freezers.³⁷ The National Cold Chain Equipment inventory indicated inadequate and aging cold chain equipment, lack of maintenance system at all levels, lack of spare parts, and the use of several makes of ice-lined refrigerators (ILRs) and deep freezers (DFs).³⁸ Availability of cold chain guidelines, logistic materials, and tools for monitoring storage temperature (thermometers, VVMs, temperature logging charts) at public health centers (PHCs) are also among others that could encourage cold chain handlers to properly practice vaccine cold chain management.^{27,39}

The maintenance of vaccines in the cold chains requires adequate cold chain infrastructure, trained staff, and compliance to the standards. Cold chain handlers' work experience, educational status, training on vaccine management, and utilization of EPI guidelines were among the factors that affect cold chain management practice. ^{14,21,23,40,41} Having more work experience, in-service training, and using EPI guidelines at work were factors that improved health professionals' knowledge about cold chain management and need to be maintained. ⁴²

The cold chain is assumed to be at the highest risk, particularly in countries where power supply, transportation, and skilled human-power are unreliable; cold chain maintenance is underdeveloped, and temperature monitoring is

challenging^{32,41} Health centers in developing countries face this risk due to the constraints of unsustainable electricity supply, inadequate and improperly set up storage facilities, perceived poor supervision and monitoring of cold chain management by the regulatory authority, traceability, and management of product recall. 35,40,43,44 Ethiopia is not the exception to this reality. Public health centers of Jimma zone, akin to other health facilities in Ethiopia, operate under unreliable power sources and inadequate material, financial, and human resources that limit the provision of essential immunization services to its vulnerable population segments. Being in tropical climates, temperature fluctuation in the districts of Jimma zone also exposes vaccines to extreme temperatures. 45 The majority (89%) of the population in Jimma zone dwellers are rural, and an estimated 60-80% of child health problems attributable to vaccine-preventable diseases. 46

Although several outbreak investigations and studies have been conducted in Ethiopia to assess vaccinators' knowledge of vaccine management, none have been undertaken or published for readers to gain knowledge about vaccine cold chain maintenance and stock management practices at public health centers in southwest Ethiopia. ^{33,42,47–50} Considering these, it would be of high importance to know how public health centers in Jimma zone have developed their cold chain, the knowledge level of cold chain handlers, and the current status of cold chain maintenance and vaccine management practice.

Method

Study Area and Setting

The study was conducted in public health centers of selected districts in Jimma zone. It is one of the 21 zones in Oromia Regional State. Jimma town is a zonal administrative town located 345 kilometers from the southwestern direction of the capital of Ethiopia, Addis Ababa. The zone consists of 20 rural districts and one special town administration (Agaro Town), with 558 total kebeles (the smallest administrative units) comprised of 46 small urban and 512 rural kebeles. As per Jimma zone health bureau statistics, the zone has 5 public hospitals, 128 health centers, 558 health posts, and a total of 1115 health center workers.

Study Design and Population

An institutional-based cross-sectional study design was employed using both quantitative and qualitative data collection techniques. The study population comprised public health centers in Jimma zone providing immunization services for at least 1 year in selected districts of Jimma zone, selected cold chain equipment, selected cold chain handlers from the pharmaceutical store, maternal and child health, immunization, and drug dispensary units and selected key informants (pharmacy heads or logistic officers, EPI focal persons, facility heads and EPSA cold room managers) responsible for vaccine cold chain maintenance in the final stage of cold chain operation both at EPSA hub distribution points and health centers' immunization service delivery points, records and reports used for vaccine management before the commencement of the study at selected public health centers. List of WHO tracer vaccine is presented in supplementary material (Supplementary Table 1).

Sample Size Determination and Sampling Techniques

The sample size for evaluating knowledge status of cold chain handlers was determined using a single population proportion formula $[n = [(Z\alpha/2)2.P (1-P)]/d2]$ by assuming a 95% confidence level (Z $\alpha/2 = 1.96$) and a margin of error of 5%; p = proportion of cold chain handlers who knew and listed heat sensitive vaccines from a similar study done in East Gojam, Ethiopia (96.7%).⁴⁸ With 15% accounting for nonrespondents, the final sample size of vaccine cold chain handlers was 165. The sample size of public health centers was determined using the USAID/DELIVER PROJECT guideline and a logistics indicator assessment tool (LIAT), which suggests that the minimum of 15% of the targeted health facilities could be considered representative of the reference population for evaluating pharmaceutical management when budget and time constraints are present.⁵¹ As per the guideline, the final sample size would be 41 public health centers. A cluster random sampling technique was employed for the health center for evaluation. The level of the district was used as the cluster. The sample comprised of selected health centers was proportional to the number of health centers in each cluster. The sampling strategy and allocation of public health centers are presented in supplementary material [Supplementary Figure 1 and Supplementary Table 2].

Sixteen key informants were purposively interviewed based on their experience and position in their organizations; 12 selected from all three clusters of districts in the Jimma zone, and four key informants selected from the EPSA Jimma hub. A stratified purposeful sampling technique was employed to select the key informants within the districts and Jimma EPSA hub. The sampling technique used for the qualitative study is presented in a supplementary table [Supplementary Table 3].

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Study Variables

- Variables that describe the status of cold chain management at public health centers: availability of standard cold chain resources (functional refrigerators, freezers, cold boxes, ice packs, thermometers, recording and control tools), vaccine stock management practice, availability of guideline for cold chain management
- Variables that describe cold chain handlers: age, sex, professional status, years of experience/length of service, training status, knowledge of personnel on cold chain management and supervision from higher level.

Data Collection Tools and Procedures

The LIAT⁵² and effective vaccine management assessment tool (EVMAT)⁵³ were adopted for the quantitative part while the Logistic System Assessment Tool (LSAT)⁵¹ was also adopted to develop the key informant interview guide. The key informant interview guide of standard open-ended questionnaires obtained in-depth information regarding vaccine cold chain management practice. A self-administered questionnaire (SAQ) addressing knowledge items with a reliability coefficient (Cronbach's alpha) of 0.78 was used to assess the knowledge level of cold chain handlers. A pretested observational checklist witnessed the status of cold chain management practices. A pretested observational checklist was utilized to witness on spot cold chain status of cold chain management practices. Availability, functionalities, and physical verification of both electrical and non-electrical cold chain equipment were also observed.

Data Processing, Analysis and Quality Assurance

The data collection tool was pretested before the data collection. The collected data was summarized on the same day as collection and checked by the principal investigator for consistency, regularity, and completeness. The Statistical Package for Social Sciences (SPSS) version 22 was used for analysis. Chi-square (X^2) test determined the association of vaccine cold chain management practices with various independent variables. A p-value of <0.05 was considered statistically significant. The qualitative data were transcribed, summarized into the key thematic area, presented in narrating the findings, and triangulated to provide meaningful information.

Operational Definitions

Cold Chain Handlers

Cold chain handler is the key person for maintaining, monitoring and managing of cold chain and responsible for safe storage of vaccine in their respective units of public health centers.⁵³

Knowledge Status of Vaccine Cold Chain Handlers

The total questions were 15, covering vaccine vial monitor (VVM), shake test, multi-dose vaccine vial policy (MDV-VP), ice packs conditioning, FEFO vaccine flow, and temperature monitoring. The number of items (15) was consistent and good enough to assess knowledge status of cold chain handlers as reflected by acceptable internal reliability coefficient, Cronbach's alpha of 0.78. The number of correct responses ("YES") that individuals received out of the 15 items determined their level of knowledge. The correct response to an item received one, whereas an incorrect one received zero. The scale was divided into poor knowledge, fair knowledge, and good knowledge. Any respondent who scored between 0 and 5 questions (0-33%) was considered as having poor knowledge, a score between 6 and 10 (34-66%) was considered as having moderate knowledge and scoring 11 and above (67-100%) was considered as having good knowledge in vaccine cold chain handling and management.⁵⁴

WHO Vaccine Storage Practices Code

Code 1: BCG and measles vaccine in the lower basket; Code 2: T-series and Hepatitis B vaccine in upper right basket; and Code 3;- diluents, returned partially used and unused vials in the upper left basket. It is good when all three codes are practiced correctly; it is fair if at least two of three codes are practiced and graded as poor storage practice if only one code is practiced.²⁹

Cold Chain Maintenance (Practice)

Cold chain is said to be properly maintained if and only if there is proper temperature monitoring (twice daily monitoring), proper review of vaccine vial monitoring to check exposure of vaccine to heat, undertaking shake test to check exposure of vaccine to freezing temperature, adherence to the first expiry first out vaccine flow in distributing vaccine to users, regular cleaning and defrosting of refrigerator/fridge ice and timely cold chain equipment maintenance during breakage as per WHO recommendations.⁵⁵

Table I Background Characteristics of Cold Chain Handlers, Management Support and Fund Availability at Study Public Health Centers in Jimma Zone, October 2019

| Public health centers' and cold chain handlers' background characteristics | | | Frequency (percentage) | |
|--|---|--|---|--|
| Demographic variables (n=148) | Educational status | Technician/diploma Graduate degree Post-graduate degree | 56 (37.8%) 79 (53.3%) 13 (8.9%) | |
| | Experience at work | Less than I year I to 5 years 6 to 10 years >10 years | 9 (6.1%) 63 (42.6%) 54 (36.5%) 22 (14. 8%) | |
| Training (n=148) | Training status | Received Never received | 104 (70.3%) 44 (29.8%) | |
| | Type of training | Received pre-service Received in-service | 22 (14.9%) 82 (55.4%) | |
| | Frequency of in-service training | Once Twice Trice | 22 (14.9%) 47 (31.8%) 13 (8.7%) | |
| Supportive supervision of public health centers | Supervised in one month prior to data collection (n=41) | Yes No | 16 (39.1%) 25 (60.9%) | |
| | Received feedback of supportive supervision (n=16) | Yes No | 14 (87.5%) 2 (12.5%) | |
| Management support and fund availability at public health centers for cold chain m | | hain maintenance (n=41) | Frequency (percentage) | |
| PHCs had support from their management | | Yes No | 22 (53.7%,) 19 (46.3%) | |
| PHCs had funds available | | Yes No | 21 (51.2%) 20 (48.8%) | |
| Reported annual budget from public health centers (n=21) | | Less than 150,000 Ethiopian birr Did not know their budget figure | 19 (90.5%) 2 (9.5%) | |
| Frequency and funding regularity (n=19) | | Bi-annually Annually | 9 (42.9%) 10 (47.1%) | |

Results

General Information of Public Health Facilities and Cold Chain Handlers

Out of 165 self-administered questionnaires, only 148 were correctly filled and returned by cold chain handlers, providing a response rate of 89.7%. More than half (55.4%) of the respondents were female, and 40.5% were between 25–29 years of age. A little more than (53.3%) have a graduate degree, (42.6%) have worked for about 1 to 5 years, and 55.4% had got in-service training, while only 31.9% received it twice during their stay at public health centers. Just above one-third

(39.1%) of public health centers had received supportive supervision from the districts/regional health office within the month before data collection. More than half of public health centers had their management support for funding cold chain maintenance. Nineteen out of 21 public health centers reported that they received an annual budget of less than 150 thousand Ethiopian birr (ETB) on either an annual or bi-annual basis (Table 1).

One of several difficulties mentioned as impeding the health center vaccine cold chain performance is a lack of consistency in cold chain handler training and supervision, for example: "I have been working here for the past two

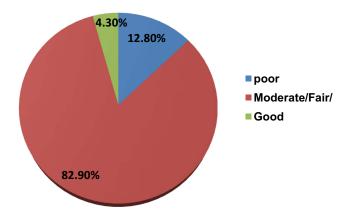


Figure 1 Knowledge level for cold chain handlers at study public health centers in limma zone. October 2019.

and a half years. I had the opportunity to train in cold chain logistics before, but my health facility has never supervised" (EPI focus point at one health center); "External supervision has typically followed their timetable, although I wouldn't call it consistent ... the trained personnel continues going away, so we can't carry out our internal supervision" (delegate for director of one public health center).

Knowledge Level of Cold Chain Handlers at Study Public Health Centers

Regarding the knowledge level of cold chain handlers, the majority of participants (82.9%) have a moderate (fair) level of knowledge (Figure 1). Support findings show additional points concerning knowledge of cold chain handlers related to individual questions on the assessment and knowledge scores for cold chain handlers at public health centers in the Jimma zone [Supplementary Tables 4 and 5].

Cold Chain Maintenance Practice

In most public health centers, ice-lined refrigerators (ILRs) and deep freezers (DFs) were adequately maintained and correctly located (at least 10 cm) away from the wall and away from direct sunlight. Half of ILRs (52.2%) had do's and don'ts, and most (95.1%) ILRs had their electric plugs secured in place. Diluents of BCG and measles supplied along with vaccines were adequate and were stored in ILRs as per the guidelines in only 34 (82.9%) public health centers. Frozen vaccines were seen in two public health centers visited (Table 2). At the time of visit, out of 41 public health facilities with functional refrigerators, 19 (46.3%) of them experienced poor storage practice as per the WHO cold chain storage code (Figure 2). Twenty-one

(51.2%) public health centers visited had done twice daily monitoring of temperature in logbooks, but only 8 (19.8%) had weekly monitoring of temperature logbook by the officer in charge. The majority (85.4%) of public health centers visited had refrigerators within the recommended temperature range (Figure 3).

Vaccine Stock Management Practices

Most of the public health centers visited during the study (85.4%) had recorded all parameters for vaccines, logistics, and diluents. Distribution registers were used for vaccines and logistics as per the norm in 38 (92.7%) public health centers. Thirty-seven out of 41 (90.2%) public health centers had a stock register in place, of which only 19 (46.3%) public health centers had updated records of vaccines. The majority of the public health centers (36.6%) did not have a visible emergency or contingency plan. Twentyfour (58.5%) public health centers had a paper-based system for vaccine and logistics stock management (Table 2). Additional cold chain practice characteristics, such as adherence to the WHO Cold Chain Policy, the implementation of multiple cold chain management procedures, and the use of the EPI guideline at public health centers in the study area, are provided to support the finding [Supplementary Figure 2].

Availability of Power Sources, Standard Cold Chain Equipment and Tools at PHCs

The majority of public health centers have operational water and electricity that aid vaccine cold chain maintenance. All public health centers have working stabilizers with plugs and sockets and have access to at least one of the main power supplies. The majority of public health centers, 32 (78.1%), have working thermometers. Most of them, 32 (92.7%), utilize electricity as the main power supply while 18 (43.9%) have alternative sources of power. Only around one-third (31.9%) use alternative power sources such as gas/backup generators at the moment of on-spot observation (Table 3).

Availability of guidelines in logistics management at public health centers was revealed as the major problem in acquiring vaccines, for example: "We do not have guidelines to follow in this all process of vaccine order processing & receipt and overall managements of cold chain commodity level at the center" (pharmacist in charge of one health center).

Table 2 Cold Chain Maintenance and Vaccine Stock Management Practice at Public Health Centers in Jimma Zone, October, 2019

| Characteristics of ice-lined refrigerators and deep freezers (ILR/DFs) (n=41) | Frequency (percentage) | |
|---|---------------------------|--|
| ILR adequately maintained (not cracked) | 36 (87.8%) | |
| ILR supported by wooden rack | 29 (70.7%) | |
| Monitoring chart was up to date | 18 (43.9%) | |
| Expiry date mentioned on chart | 14 (32.1%) | |
| ILR and DFs were away from direct sunlight | 38 (92.7%) | |
| ILR distance from wall >10cm | 38 (92.7%) | |
| ILR/DF had do's and don'ts sticker on the door | 21 (52.2%) | |
| Electric plugs were secured in place | 39 (95.1%) | |
| Vaccine storage and cold chain maintenance practice at PHCs (n=41) | Frequency (percentage) | |
| Freeze sensitive vaccines away from compartment lining | 36 (87.8%) | |
| OPV and freeze-dried vaccines (measles, BCG and other conjugate vaccines with diluents were stored on top shelf of ILR) | 34 (82.9%) | |
| Freeze-sensitive vaccines (all DTP, DT, Td, TT, HepB, DTP+HepB, DTP+HepB+Hib, Hib, HPV, rotavirus) were stored on middle or lower shelves | 32 (78.1%) | |
| Boxes containing vaccines with darker VVMs and boxes containing opened vials and closer expiry dates were placed in "use first section" | 28 (68.3%) | |
| Presence of vaccines or diluents in the refrigerator door shelves | 7 (17.1%) | |
| Reconstituted BCG, measles vaccines found stored | 12 (29.3%) | |
| Items other than vaccines (Antisera, HIV kit, diluents) stored inside ILR | 16 (39%) | |
| All diluents placed inside ILR on the bottom shelf | 38 (92.7%) | |
| Opened vial are stored separately inside ILR | 12 (29.3%) | |
| All vaccines kept in the basket in the ILR | 39 (95.1%) | |
| Presence of any vaccine vial beyond usable VVM in the ILR | 8 (19.5%) | |
| Presence of expired vaccines in ILR/DF | 11 (26.8%) | |
| Presence of frozen vaccines in ILR/DF | 2 (5.2%) | |

(Continued)

Table 2 (Continued).

| Ice packs correctly placed for freezin freezer (n=28) | 25 (89.3%) | |
|---|---------------------------|------------------------|
| Correct use of ice packs | 21 (51.2%) | |
| Vaccine stock management prac management information system health centers (n=41) | Frequency (percentage) | |
| Vaccine management stock register v | was in place | 37 (90.2%) |
| Vaccine management stock register w updated | 19 (46.3%) | |
| Nil stock of any vaccine found during | g the visit | 15 (36.5%) |
| All the vaccine vials have proper rea | dable labels | 29 (70.7%) |
| Stock of vaccines charted | 25 (61%) | |
| All parameters for vaccines, logistics are recorded | 35 (85.4%) | |
| Returned vials from the field are ent stock register | 14 (34.1%) | |
| Distribution register in use for vacci logistics as per norm | 38 (92.7%) | |
| Expired and wasted vaccines are documented in stock register | | 32 (78.1%) |
| Physical counting of vaccine stock is done at least once in last 3 months | | 7 (17.1%) |
| Physical stock of (BCG/measles) is matching the stock register for that day Vaccine and logistics stock management updated till last transaction | | 16 (39%) 31 (75.6%) |
| Chart/SOP on ILR/DF/vaccine/Ice-pack arrangements available | | 29 (70.7%) |
| Emergency/contingency plan visible | | 15 (36.6%) |
| System in use for vaccine and | Paper | 24 (58.5%) |
| logistics stock management | Computer- based | 0 |

Factors Related to Vaccine Cold Chain Management Practices

Professional qualifications, educational status, work experience, types of vaccine cold chain training, availability of funds for cold chain maintenance, adherence to the WHO open vial policy, and availability of cold chain equipment at public health centers were all factors considered and

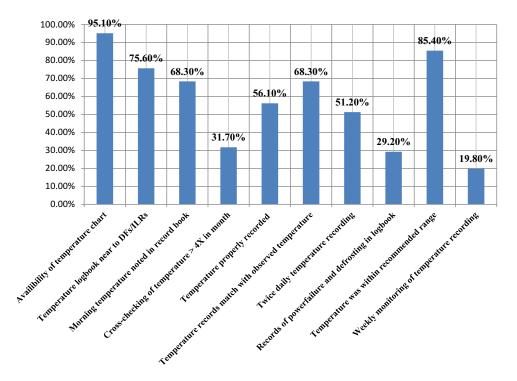


Figure 2 Vaccine storage practice at study public health centers in Jimma zone, October 2019. **Abbreviations**: DFs, deep freezers; ILRs, ice-lined refrigerators.

evaluated for their effects on vaccine handling practices. A test of association between cold chain handlers' years of service in vaccine cold chain management, types of training on vaccine cold chain management, availability of funds for cold chain maintenance, adherence to cold chain WHO open vial policy, availability of cold chain equipment showed significant associations with vaccine cold chain management practices at public health centers (Table 4).

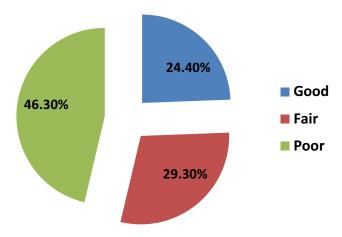


Figure 3 Temperature monitoring and recording practices at public health centers in limma zone. October 2019.

Challenges Confronting Public Health Centers in Managing Vaccine Cold Chains and Proposed Solutions (Key Informants' Suggestions)

Shortage and turnover of trained manpower, inadequate budget, electrical power interruption, shortage of cold chain equipment, and lack of timely maintenance for cold chain equipment were among the main challenges explored by the study. One of the key informants stated that "as to me one the barriers that comes to me at this moment in time is a shortage of budget for effective vaccine cold chain equipment maintenances. Besides I believe the management support is also not to level I have expected that they needs be proactive in such situation."

Limited training for cold chain handlers hampers public health centers' cold chain management practices. For instances, one EPI focal person at study health centers noted that "I have not had a chance to train in logistics/drug management let alone specific cold chain management but I'm working here, I'm never supervised but I normally write and forward a list of out of stock vaccine to the In-Charge and wait."

Capacity building, distribution of cold chain equipment with adequate spare parts, solving electric power

Table 3 Availability of Cold Chain Resources at Study Public Health Centers in Jimma Zone, October 2019

| Public health centers' cold chain resources (cold chain infrastructure, equipment, cold chain tools and | | Availability, n (%) | | |
|---|---|---|--|--|
| power sources) | | | Yes | No |
| Public health centers' infrastructure | Operational water Operational electricity Operational vehicle Fire safety equipment | | 32 (78.1%) 35 (92.7%) 3 (8.6) 1 (2.9) | 9 (21.9) 5 (7.3%) 32 (91.4) 34 (97.1) |
| Cold chain equipment | At least one functional refrigerator At least one functional freezer Functional vaccine carrier Functional, separate stabilizer, plug and socket Functional cold boxes Working thermometer inside freezer Ice packs Table for conditioning of ice packs Foam pads | | 41 (100%) 28 (68.3%) 32 (78.1%) 41 (100%) 37 (90.2%) 32 (78.1%) 39 (95.1%) 30 (73.1%) 28 (68.3%) | 0 13 (31.7%) 9 (21.9) 0 4 (9.8%) 9 (21.9) 2 (4.9%) 11 (27.9%) 13 (31.7%) |
| Cold chain management tools | Temperature record (log) book Temperature recording sheet EPI SOP guideline | | 37 (90.2%) 38 (92.6%) 17 (41.5%) | 4 (9.8%) 3 (7.4%) 24 (58.5%) |
| Source of power supply in public health centers | At least one source | | 41 (100%) | 0 |
| | Main source | Electricity Have non-electricity (solar) | 38 (92.7%) 3 (7.3%) | 3 (7.3%) 38 (92.6%) |
| | Alternative source | Standby generator Solar panel Electricity | 13 (31.7%) 4 (9.8%) 38 (92.7%) | 28 (68.3%) 37 (90.2%) 3 (7.3%) |

interruption and strict adherence to cold chain management manuals were suggested as the proposed solutions to overcome cold chain management challenges. One key informant stated: "putting cold chain medicines in a circle on icepack compromises cold chain as it may cause freezing of temperature-sensitive medicines. At the

end, due to careless storing, handling and administering, these products may lose their potency."

Availability of cold chain equipment was perceived to be very important for effective vaccine cold chain management. One key informant stated: "availability of fridge tags which record temperature continuously and report the out

Table 4 Bivariate Analysis of Study Variables on Vaccine Cold Chain Management at Study Public Health Centers in Jimma Zone, October 2019

| Variables | X ² test | p-value |
|--|---------------------|---------|
| Years of service in vaccine cold chain management | 6.47 | 0.016* |
| Types of training on vaccine cold chain management | 10.68 | 0.004* |
| Professional qualification of the vaccine handlers | 5.65 | 0.164 |
| Educational status of CCHs | 3.32 | 0.311 |
| Knowledge level of CCHs | 12.57 | 0.002* |
| Availability of fund for cold chain maintenance | 19.01 | 0.008* |
| Adherence to cold chain WHO open vial policy | 9.809 | 0.021* |
| Cold chain EPI guideline utilization | 2.98 | 0.373 |
| Availability of cold chain equipment | 14.98 | 0.015* |

Notes: *p-value <0.05 is statistically significant. **Abbreviation**: CCHs, cold chain handlers.

of range temperatures were good practice on vaccine cold chain management that needs to scaled up." Another key informant described that "availability of a solar fridge is a good practice. Since it doesn't need electric power/kerosene and has self-adjustable constant temperature, it maintains temperature-sensitive medicines at a recommended temperature at any time."

Discussion

The study was intended to reflect on the current state of cold chain maintenance, identify knowledge of cold chain handlers, and improve the cold chain management practices at public health centers in Jimma zone, southwest Ethiopia. Most of the respondents were between the ages of 25–29 years. It represents a population that is very active in health centers. Despite variances in kind, regularity, and frequency of training, the majority (70.3%) of respondents trained regularly. This finding is close to the studies done in the northwest region of Cameroon, ⁴⁰ the coast region of Tanzania, ⁵⁶ and southern Nigeria. ⁵⁷ It is in disagreement with the findings from central Ethiopia, where the majority of the health centers had neither trained personnel nor a budget for maintaining the cold chain. ³³

A well-operated and managed public health center with knowledgeable cold chain handlers is fundamental for proper cold chain management. Knowledge of vaccine cold chain handlers on how to operate cold chains varies among individuals. For instance, more than half of cold chain handlers identified BCG and OPV as heat-sensitive vaccines correctly. whereas more than half of them identified DPT and TT as freeze-sensitive vaccines correctly. This finding is in line with the study done at Dschang.²² More than two-third s demonstrated the shake test correctly, which is in line with findings in the northwest region of Cameroon. 40 However, it is higher than findings in Toronto.⁵⁸ The cold chain handlers showed inadequate knowledge on some aspects of cold chain management. This finding corroborates studies from Mozambique, 32 Tanzania, 56 Jordan, 59 and India, 60 which revealed a similar level of knowledge of cold chain handlers on the effect of freezing some vaccines, the shake test, and the correct storage temperature range at public health facilities. It also corroborates the findings from a study done in Ethiopia.³³

Although cold chain handlers had a higher level of knowledge in certain areas and a lower level in others, more than half of them had a fair level of knowledge. This finding corroborates the assessment done in the northwest region of Cameroon⁴⁰ and the coastal region of Tanzania, where respondents' knowledge was average (moderate).⁵⁶ However, this contradicts a report from Kelantan,

Malaysia, which revealed that 78.7% of respondents have sufficient knowledge of cold chain operations.⁴¹ This difference might be attributable to the level of training and education of cold chain handlers.

Provision of adequate equipment and implementation of a properly designed monitoring and control system are critical components for the success of cold chain management. Most cold chain equipment, such as operational deep freezers, inclined refrigerators, working vaccine carriers, voltage stabilizers, and ice-packs were nearly uniformly accessible throughout health centers. These findings are similar to those reported in the northwest region of Cameroon, 40 central Ethiopia, 33 Malaysia, 61 Southern Nigeria, 22 and South India. 60 Inadequate maintenance and lack of standby generators, and shortage of gases and thermometers are among the main problems experienced in controlling cold chains at public health centers. It corroborates findings from studies conducted in Cameron, 21 Tanzania, 22 and Nigeria, 56 which indicated that electricity failure in urban areas, a shortage of gas in rural regions, and lack of a contingency plan were among the considerable challenges.

Cold chain handlers with more than five years of work experience in vaccine cold chain management and training on cold chain management had better practice than those with less than five years of work experience and training on either vaccine cold chain management or equipment maintenance, according to the chi-square test. Similarly, the study in Thailand identified that healthcare workers who had sufficient training on cold chain handling and management performed better on managing cold chain management than those who had no training (p < 0.001).⁶² A finding in Ethiopia identified that years of service in the immunization program showed a statistically significant association with the practice of cold chain management (p <0.05).³³ Availability of funds at public health facilities for cold chain maintenance, adherence to cold chain WHO open vial policy, and availability of cold chain equipment were among the factors associated with vaccine cold chain management practices. This finding is in line with the studies done in south Nigeria, 35 northwest Cameroon, 40 Surat in India, 63 and Cebu in Philippines. 64

Conclusions and Recommendations

The knowledge level of the majority of cold chain handlers was not good. Although the majority of public health institutions' storage conditions are acceptable, some

nevertheless fall short of the recommended storage conditions required for the success of cold chain management. Unreliable power supply at public health centers appears to be the major challenge in maintaining the recommended temperature range. Adherence to good storage practices like arrangement of products within the refrigerator, temperature monitoring and recording also needs an attentive eye from cold chain handlers. Appropriate and coordinated efforts are required to ensure the availability and maintenance of cold chain equipment. Of the challenges revealed by this study, budgetary constraints require the attention of higher-level management while most of the rest are correctable by low-level administration at public health centers. Therefore, the directors of health centers need to ensure the availability of cold chain equipment with all recommended tools, materials, and resources through a chain of communication between themselves and higherlevel health offices. They also ought to map access to the power supply and minimize power interruption at health centers by having at least one standby as the source of power through intersectional collaboration and community participation. Directors of health centers also need to provide the proper, comprehensive, and continuous training for cold chain handlers at a reasonable periodicity to improve cold chain management practice. They must also provide a timely repair of cold chain equipment besides frequent internal supervision of cold chain handlers.

Store managers need to ensure that vaccine is stored properly per WHO storage code. In addition, cold chain handlers need to maintain acceptable vaccine storage conditions by appropriately implementing the cold chain policy and EPI-SOP and placing contingency plans in place during a power outage or equipment failure.

Implications, Limitations and Scope of the Study

This study is likely to have managerial and social ramifications on both empirical and theoretical levels. The significance of this study at empirical level includes identifying a significant management gap in terms of cold chain equipment maintenance, cold chain handler knowledge status, cold chain management practices, and the administration and supervision of a health center's cold chain unit. The study reminds district health service managers not only to assure the availability of cold chain equipment at the public health centers, but also to monitor vaccine wastage to enhance program quality and efficiency. Theoretical implications of this study are that it

draws on how developing countries with public health facilities in tropical climates cope with the challenges of inadequate temperature monitoring, unreliable equipment, and unsuitable refrigerator utilization for vaccine cold chain management. The study has managerial implications where the integration of cold chain handlers' training, supportive supervision, and mentoring on immunization programs is essential for effective cold chain management.

The study findings and their applicability are limited to public centers in Jimma Zone rather than the entire country. However, had the study's scope expanded to include public health institutions across the country, more significant results would have been reduced. In addition, the study provides an overview of vaccination handling and storage information. There was, however, no revisit to ascertain any change in knowledge and practice level of respondents. Despite these limitations, the study produced valuable findings that might help enhance vaccine cold chain management at public health centers in Jimma zone.

Abbreviations

BCG, Bacillus Calmette Guerin; DPT, Diphtheria, Pertusis, Tetanus, Hepatitis B, and Influenza type b; DFs, deep freezers; EPI, Expanded Programme on Immunization; FEFO, first to expire first out; ILR, ice-lined refrigerator; FMOH, Federal Ministry of Health; LIAT, logistic indicators assessment tool; LSAT, logistic system assessment tool; OPV, oral poliovirus vaccine; EPSA, Ethiopian Pharmaceutical Supply Agency; PHCs, public health centers; TT, tetanus toxoid vaccine; UNICEF, United Nations Children's Fund; EVMAT, effective vaccine management assessment tool; VVM, vaccine vial monitoring; WHO, World Health Organization.

Data Sharing Statement

The data sets generated and/or analyzed during the present study are available from the corresponding author on reasonable request.

Ethics Approval and Consent to Participate

The investigators received ethical approval of the research from the ethics committee of Jimma University, Institute of Health. Letter of permission was also received from both Oromia regional state and Jimma zone health department and each selected public health center in a subsequent manner. Written and verbal informed consent was obtained from

study participants prior to undertaking data collections. The purpose of the study was explained to the study participants; privacy and confidentiality were ensured. The respondents' right to refuse or withdraw from participating in the study was fully acknowledged. The participants' privacy was confidential and anonymous. This study was conducted in accordance with the Declaration of Helsinki.

Consent for Publication

The manuscript did not contain individuals' detailed data in any form and information related to publishing the study findings was addressed; participants gave their consent to publication of anonymized responses.

Acknowledgments

The author would like to thank data collectors and all study participants (the focal personnel, supply chain coordinators, cold chain handlers, health facilities head and directors of central Ethiopian Pharmaceutical Supply Agency [EPSA] and coordinators and managers at Jimma EPSA hub) who contributed to the generation of valuable information during the data collection.

Funding

There is no funding to report.

Disclosure

The author declares no financial or non-financial conflicts of interests in this work.

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