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Original Article

Vaccine Cold Chain Management in Public Health Facilities of Oromia Special Zone, Amhara Region, Ethiopia: Mixed Study

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Abstract

Background: Effective vaccine cold chain management and well maintained equipment are the keys to safe vaccine storage and delivery.

Methodology: A facility based explanatory sequential mixed method was used. The quantitative method used an institutional based cross sectional study design to assess the vaccine cold chain management in all (27) health facilities. Then, a phenomenological study design was employed among key informants and content analysis was performed using NVivo 11 plus.

Results: Proper vaccine storage was observed in 17 (63%) health centers and only 13 (48.1%) health facilities had satisfactory cold chain infrastructure, while 17 (63%) had good cold chain practices. Placement of vaccines during immunization session, checking the signs of damage, storage of food or any drugs other than vaccines, checking, availability of deep freezer, cold box and functional thermometer has a significant association with vaccine storage. Key informants stated that cold chain infrastructure, temperature monitoring, stock management and immunization practice affect vaccine storage.

Conclusion: The availability of cold chain equipment in health facilities was below average and the practice of cold chain management in health facilities was average. Improving the availability of the cold chain equipment and undertaking regular support and follow up are recommended.

Keywords: Cold chain management; Vaccine; Public health facilities

Introduction

Vaccination is a core component of the human right to health and over 100 million children are immunized every year before their first birthday [1]. Despite this success, almost 20% of all children born every year and millions of children in developing countries do not get complete immunizations scheduled for their first year of life [2] and vaccine preventable diseases remain a major cause of morbidity and mortality [1].

Vaccines are sensitive biological products that can easily be destroyed if handled incorrectly [3]. The type of antigen used in their preparation and formulations affects their storage [4]. Excessive heat, cold, or light exposure can damage vaccines and result in reduced potency [5]. Further exposure to improper conditions will further result in potency reduction [6]. This storage and handling errors resulted in revaccination as a result of inadequate immune responses and poor protection against disease, resulting in loss of patients' confidence [6,7].

Although effective management and well maintained equipment are the keys to safe vaccine storage and delivery [3], various factors have contributed to compromised cold chain logistics across the developing world [8,9]. In health facilities where vaccine storage equipment available, there is inadequate monitoring of cold storage units [10-12] and inadequate implementation of vaccine management guidelines [6,13-18].

Furthermore, the absence of appropriate cold chain equipment to store and transport vaccines [19], absence of systems to monitor the temperature of thermo sensitive vaccines [11,20-23] and insufficient cold chain capacity [24] are common problems associated with vaccine storage. The availability of sufficient storage capacity for existing vaccines in 2014 was 43% in low and lower middle income countries [25], lack of access to generators [26], weak vaccine inventory control and logistics management information system and expiry were also factors responsible for vaccine wastage [27-29]. Besides, when there is an equipment failure, larger quantities of vaccine can be destroyed [3]. Thus, cold chain systems are struggling to efficiently support national immunization programs [8].

Vaccine supply is the backbone for immunization, as health is essential for the development of a country [30]. Availability and effective management of the vaccine cold chain system are crucial to the optimal performance of an immunization program and the ability to achieve comprehensive and equitable immunization coverage. To do so, considerable investments have been made to ensure that children and adults throughout the world have equitable access to safe and effective vaccines [31]. Therefore, this study assessed the vaccine cold chain infrastructure and management of public health facilities in the Oromia special zone.

Methodology

Study area and period

The study was done in Oromia special zone public health facilities, Ethiopia, from September 1 to September 30, 2019. The Oromia Special Zone is located 326 kilometers away from Addis Ababa, the capital city of Ethiopia. The special zone had 2 hospitals, 28 health centers, and 115 health posts with a tropical climate that could compromise the potency of vaccines.

Study design

An explanatory sequential mixed method was used. An institutional based cross sectional and phenomenological study design was used.

Sources and study population

All public health facilities (28 health centers and 2 hospitals) that had been offering immunization services.

Sample size determination and sampling procedures

All public health facilities that had been involved in offering immunization services were included. But one health center and both hospitals were excluded due to interruptions in rendering vaccination services. Key informants were selected purposively by Woreda Health Office Vaccine Logistics officers. The sample size for the phenomenological study was determined by the saturation of information concerning emerging themes. Thus, 13 key informants (4 midwives, 8 nurses, and one health officer) were included.

Data collection tools and procedures: A structured observation checklist adopted from the World Health Organization (WHO) was used to assess the practice and system of the vaccine cold chain of health facilities [32]. The vaccine cold chain practice was assessed using a total of 25 questions in 9 domains. The quantitative data were collected by three experienced pharmacists.

For the phenomenological study, the semi structured interview guide was initially prepared in English and then translated to Amharic and finally back translated into the English language to maintain consistency and standardization of the instruments. The principal investigator conducted an in depth interview, which lasted 15-30 minutes. The interview was done in Amharic and all interviews were audio recorded and transcribed verbatim. We followed the methods of Mohammed et al. 2021 [33].

Issues of reflexivity

The principal investigator status as an insider: The principal investigators being senior pharmacy professionals offer certain strengths and limitations for this study. They operated with awareness of insider bias. They practiced non-judgment and with the awareness of professional relativity.

Data management and analysis: Data entry was done in EpiData version 4.6 and analyzed by Statistical Package for Social Sciences version 20. Fisher exact test was used to test the association with 95% confidence intervals and variables with $p<0.05$ were taken as statistically significant. All written transcripts were read several times to obtain their overall feelings and all sections of original transcripts were translated into English to facilitate coding line by line. The analysis was done by NVivo 11 plus using the principles of content analysis. A narrative strategy was employed for the presentation of qualitative findings. Key informants professions, sex and work experience were used to elucidate their verbatim portray.

To assure the quality of the data, a standard questionnaire was used and more than one investigator was involved. Moreover, multiple methods were used and the Amharic version of the transcript was also brought back to key informants and was signed.

Operational definitions

Vaccine storage practice: Vaccine storage practices in the ice-lined refrigerator were graded based on the observation, with respect to three different storage criteria namely, (1) storage of Bacillus Calmette Guerin (BCG), Oral Polio Vaccine (OPV) and Measles vaccine in the lower basket or on the top shelf; (2) Injectable Polio Vaccine (IPV), Penta-valent Vaccine (PV), Pneumococcal Conjugate Vaccine (PCV), Tetanus Toxoid (TT) and Rotavirus vaccine in upper right basket and middle or lower shelves; and (3) diluents, returned partially used and unused vials in the upper left basket, and middle or lower shelves in top opening and front opening vaccine refrigerators. If all three were correctly stored, it was considered as good practice, if two and only one were correctly stored, it was graded as fair and poor practice, respectively [34].

Satisfactory infrastructure: Health facilities that scored greater than the mean score.

Good practice: Health facilities or vaccinators and vaccine handlers that scored greater than the mean score.

Results

All facilities had at least one functional refrigerator, while 13 (48.1%) had at least one functional freezer. The store only accommodates peak stock levels in 18 (66.7%) health centers. The majority (8) of key informants revealed that there is not enough cold chain equipment to manage vaccines in health facilities. The key informant portrayed: “There are a number of fridges available at our health center. But functional so far are two of them.” (Nurse, Male, 9) Another key informant also explained the situation: “We do not have enough storage for all supply.

Thus, we take and store in the health post.” (Nurse, Male, 8) Availability of sufficient frozen icepacks in the freezer was 21 (77.8%). An eight year experienced nurse said: “There are not enough ice packs to use a cold box. There is also a problem with making an ice pack."

Access to at least one power supply was reported in 19 (70.4%) health centers. All key informants mentioned the electrical cut off and one key informant described this problem: "The electric power was off for a long time. We used to take vaccines to the other health center and we had a hard time." (Nurse, Female, 6)

Fifteen (55.6%) had a function generator for backup services. Half of the key informants mentioned the absence or non-functionality of the generator. It is substantiated by one of the key informants: "We did not have a power backup. The generator was non-functional for two months. Although we submitted a letter and asked them to repair, they failed to fix." (Midwifery, Male, 4)

The availability of kerosene for refrigerators was 14.8% and 6 key informants portrayed that run out of kerosene were a bottleneck for vaccine storage. One of the key informants explained the scenario: "The fuel is out of stock. We asked health center management many times. They said no and still not ready to buy kerosene". (Nurse, Male, 6)

Only 4 (14.8%) health centers had trained personnel and none had spare parts for minor maintenance. All key informants said that there is no person in charge for maintenance and this was supported by one of the key informants: "There are no professionals who are trained in maintenance." (Nurse, Male, 9) The availability of a deep freezer, cold box and functional thermometer was significantly associated with vaccine storage (Table 1).

Table 1: Cold chain infrastructure and system availability in the health facility of Oromia Special Zone, 2019.

S. no	**Observed infrastructure and practice of the cold chain system**		**Frequency (percentage)**	**P value**
1	Type of cold chain equipment	Ice lined refrigerator	21(77.8)	0.15
		Deep freezer	8(29.6)	0.02
		Cold box	10(37)	<0.001
		Dometic refrigerator	6(22.2)	0.63
2	Availability of at least one functional refrigerator		27(100)	
3	Availability of at least one functional freezer		13(48.1)	0.12
4	Access to power supply	At least one source	19(70.4)	0.1
		Permanent power	8(29.6)	
5	Sources of power supply	Electricity as main source	17(63)	0.41
		Solar as main source	10(37)	
6	Availability of sufficient frozen icepacks in freezer		21(77.8)	1
7	Availability of functional generator		15(55.6)	0.42
8	Availability of kerosene for refrigerator		4(14.8)	0.12
9	Presence of a flowchart detailing what to do in case of electrical power outage		4(14.8)	0.26
10	Availability of functional car/motorbike to use in case of refrigerator failure		9(33.3)	0.40
11	Availability of functional thermometer		17(63)	0.04
12	The store can accommodate peak stock levels		18(66.7)	0.21
13	Availability of spare parts for minor maintenance		0(0)	
14	Availability of trained personnel for minor maintenance		4(14.8)	0.26
15	Availability of permanently assigned personnel for cold chain follows up		16(59.3)	0.22
16	Availability of personnel assigned during holidays/weekend for cold chain follow-up		13(48.1)	1

Proper placement of the thermometer was observed in 15 (55.6%) and 3 (11.1%) of the health centers recorded daily temperatures outside of the recommended range. On the day of the data collection, the minimum and maximum recorded daily temperatures were -2°C and 10°C with a mean and standard deviation (SD) of 4.87 ± 2.35°C. It was noted that the temperature was not recorded on charts twice daily as required in 16 (59.3%) health facilities. This was further substantiated by one of the key informants: "The refrigerator was monitored twice a day." (Nurse, Female, 11) While four key informants reject this idea and one key informant mentioned: "There is a problem with temperature recording and monitoring. Most vaccines were frozen without following the fridge. A few vaccines brought precipitate." (Nurse, Male, 9)

Planned maintenance and emergency repairs of cold chain equipment were conducted in a timely manner by 11(40.7%) and 7(25.9%). However, all key informants mentioned the absence of planned maintenance. One key informant described that: "Nothing repaired timely. It was not planned but as it happened". (Midwifery, Male, 4) Another key informant also mentioned the situation: "The head of health center and management knew but did not respond. Month passed". (Nurse, Female, 6) Proper vaccine storage was observed in 17 (63%) health centers and only 13 (48.1%) health facilities had satisfactory cold chain infrastructure, while 17 (63%) had good cold chain practices. Checking the thermometer twice daily and updating the temperature record sheet has a significant association with vaccine storage (Table 2).

Table 2: Vaccine storage temperatures monitoring in health facility of Oromia Special Zone, 2019

Sr.no	Vaccine storage temperatures monitoring	Frequency (percentage)	P value
1	Availability of daily temperature recording chart	17(63)	0.41
2	Check the thermometer twice daily	11(40.7)	0.01
3	Temperature record sheet(s) correct and up to date	13(48.1)	0.04
4	Thermometer placed in correct position	15(55.6)	1
5	Refrigerators are within the recommended temperature range	24(88.9)	1
6	Planned replacement and maintenance of cold chain equipment	7(25.9)	0.67
7	Emergency repairs are conducted in a timely manner	11(40.7)	0.44

21 (77.8%) health centers did not have correct and updated vaccine stock record books. 23 (85.2%) and 25 (92.6%) made decisions based on vaccine vial monitor status and first to expire first out. Two key informants mentioned this problem and a statement made by one key informant described: "Near expiry unopened vial vaccine supplied. We use them until their day." (Nurse, Male, 9) Another key informant also stated: "...Some vaccines enter the second stage, what we are doing is giving it first." (Nurse, Female, 11) At the time of the study, it was found that laboratory reagents, anti-rabies vaccines, and maternity medicines were placed with EPI vaccines in 5 (18.5%) health facilities. Eleven key informants described that they stored vaccines along with water and other medicines. A six year experienced nurse said: "Water, laboratory reagents and other medicines had stored together with vaccines." Checking the signs of vaccine damage and storage of food or any drugs other than vaccines has a statistically significant association ($P \leq 0.05$) with vaccine storage (Table 3).

Table 3: Vaccines stock management in health facility of Oromia Special Zone, 2019

Sr.no	Vaccines stock management	Frequency (percentage)	P value
1	Vaccine stock record books correct and up to date	6(22.2)	0.63
2	Vaccine stock record book includes diluent stock	4(14.8)	0.61
3	Check for the signs of vaccine damage	22(81.5)	0.04
4	Vaccine managers make exceptions first to expire first out rule (vaccine vial monitor status)	23(85.2)	0.12
5	Vaccine use made according to the first to expire first out	25(92.6)	0.12
6	Periodic physical inventories have been conducted	16(59.3)	1
7	Presence of food or any drugs other than the vaccines	5(18.5)	0.04

25 (92.6%) of the health centers stock of diluent corresponds to the stock of freeze dried vaccine and 21 (77.8%) facilities stored and used diluents for immunization sessions at the correct temperature. All key informants portrayed that the vaccine diluent was kept outside the refrigerator. The key informant stated: "The diluent sits in the district store. It just sits in a dry place outside the fridge." (Nurse, Female, 6) Another key informant also described the immunization practice: "We'll open a new vial when service started. Since we do not know how long it will stay, the vaccine will be available on ice pack overnight." (Midwifery, Male, 2) Placement of vaccines during the immuni-

zation session has a statistically significant association with vaccine storage (Table 4).

Table 4: Vaccines immunization practice in health facility of Oromia special zone, 2019

Sr.no	Vaccines immunization practice	Frequency (percentage)	P value
1	The stock of diluent corresponds with the stock of freeze-dried vaccine	25(92.6)	0.12
2	The needed vaccines brought to the session in a vaccine carrier with 4 conditioned ice packs, kept in shade, and not opened frequently	20(74.1)	0.004
3	Diluents for immunization sessions are stored and used at the correct temperature (2–8°C before and during use)	21(77.8)	0.15
4	Opened vials of liquid vaccines kept for the next immunization sessions	23(85.2)	0.61
5	Opened vials of freeze-dried vaccines discarded within six hours of reconstitution, or at the end of each immunization session	25(92.6)	1
6	Freeze-dried vaccines are always ordered, received and distributed with their original diluent	27(100)	
7	Checking the expiry date of vaccines before opening	25(92.6)	0.12

Discussion

Cold chain management is the most critical element of an immunization system where vaccines are received, stored and distributed. In this study, all facilities had at least one functional refrigerator. This finding was similar to the national assessment [27] and higher than the Guragie zone (22.8%) [35], the Bale zone (62.8%), central Ethiopia (57.9%) and Addis Abeba (97.6%) [36]. The results were also better than those in Cameroon [37,38]. This discrepancy might be attributed to time differences among studies, the purpose of study, sampling variation and nature of facilities included in the study.

It was found that 66.7% of health centers stores can accommodate peak stock levels. Key informants stated that the refrigerator storage space was not sufficient. The result was higher than study in Nigeria, where 30% of the health facilities had adequate vaccine storage equipment [39]. This might be because of the difference in the number and holding capacity of refrigerators and vaccine vial size. Vaccine products vary greatly in terms of their storage requirements. Meanwhile, the introduction of new vaccines will require additional cold storage capacity [40]. Vaccine expiry dates, supplementary immunization activities and cold chain reliability must be considered when calculating the capacity of cold storage [3,41]. Vaccines in single or 2 dose vials take more space, but overall fewer doses are needed since wastage rates are minimal for these products [42]. The cold chain system must have sufficient storage capacity to accommodate all vaccines and diluents [16].

The power supply was reported permanent in only 29.6% of health facilities and slightly higher than the study conducted in Cameroon [38]. The electric power supply was reported in 63% of health centers and was higher than in studies done in the Bale zone [43] but lower than Cameroon [38]. However, the electric power supply was not reliable. Electricity outage was registered on the temperature recording sheet of 10% health facilities [37]. The qualitative study also revealed the frequent and prolonged cut off power. Freezing occurred at almost every level of the cold chain distribution system, especially facilities using a sole power source [44]. In Cameroon, 26.9% of vaccine fridges were exposed to overheating and 12% were exposed to cold [37]. Although the annual cost of the solar refrigerator is 132% more than an electric refrigerator, solar refrigerators may provide savings in total cost per dose administered over electrical refrigerators [45]. Investing in a reliable device is less expensive than replacing vaccines wasted due to the loss of potency as a result of out of range temperatures [7].

The presence of a flowchart detailing what to do in case of electrical power outage was available in 14.8% of health centers. In the Bale zone, there were no posted contingency plans [43], while all health facilities in Egypt [46] and 63.3% of primary care units in Thailand had a flowchart [21]. Nearly half (55.6%) health facilities had a function generator for backup services and 14.8% had kerosene in this study. Key informants also mentioned the absence or non-functionality of the generator. The result was better than the Guragie zone [35], Philippines [26] and Nigeria [22], but lower than other studies in Ethiopia [28,47]. This might be due to financial constraints, the presence of a solar refrigerator and poor attitude towards the cold chain among professionals and administrators.

Planned replacement, maintenance and emergency repair to cold chain equipment were performed only in 25.9% and

40.7% of health centers, respectively. 21 (31.3%) health centers [28] and more than 2/3 of facilities [27] in Ethiopia had an experience of refrigerator break down and it took longer for refrigerators to be repaired [27]. In the case of their refrigerator out of function, 72.72% and 27.28% of health facilities were stored vaccines in nearby health centers and district health offices, respectively [43]. These problems were more pronounced in the urban centers compared than in the rural ones and this was due to a lack of technicians for refrigerator maintenance and budgetary constraints [28]. In order to prevent breakdown, routine maintenance is mandatory [3] and predictable failures can be planned for [48]. Key informants portrayed that there was no planned maintenance and action were taken at the time of the problem.

In this study, there were low trained personnel and no spare parts for minor maintenance as compared to other studies in central Ethiopia [47]. 1/3 (33.3%) had a car/motorbike for transportation of vaccines in case of refrigerator/power failure and this finding was consistent with studies in central Ethiopia [47], but much lower than other studies in Ethiopia [22,35]. This discrepancy might be due to financial scarcity and brakes.

The availability of permanently assigned personnel for the cold chain follow up at working hours was 59.3%. The qualitative study also revealed that the vaccine cold chain got worsened when the focal person was absent. This finding is in line with studies in central Ethiopia [47], but much lower than studies in the Guragie zone [35]. The result also showed that 48.1% of facilities permanently assigned personnel during holidays/weekends, which is in line with studies in the Guragie zone [47], but much lower than studies in central Ethiopia [35]. This might be attributed to professionals' turnover and lack of management ownership.

Out of the recommended daily temperature ranges were recorded in 11.1% of the health centers. This finding was better compared to studies conducted in Ethiopia in which 46% health posts and 23% health centers [27], seven refrigerators [28] and 36.3% of health facilities [35,47] were outside of the recommended daily temperature ranges. The problem was also observed in India [49], Philippines [26], Cameroon [37,38] and Nigeria [39]. The loss of potency is much faster when exposed to temperatures outside the recommended storage range and it may be completely destroyed due to cumulative damage [32]. This might be explained by the lack of a thermometer in the freezer, small cold storage units, failure to maintain temperature log of the freezer [10], type of refrigerator [50], absence of an alternative power source [51], intense workload [52], lack of motivation, training and supportive supervision.

With regard to the temperature monitoring chart, the finding was in line with a study in central Ethiopia [47], but much lower than the Guragie zone [35]. In this study, 48.1% updated their recordings twice daily and higher than the Bale zone (42.86%) [43] and Cameroon (40.7%) [38]. The finding was slightly lower than studies in Ethiopia: 38 (59.4%) and 37 (57.8%) complete records of the vaccine stock and temperature records, respectively [28], Thailand [21] and Egypt [46]. The discrepancy was due to the knowledge gap, poor attitude, negligence of professional and loose follow up. To maintain the quality of vaccines, it is essential to keep complete and accurate records [53].

Proper vaccine storage was observed in 63% of the health centers. This finding was better than vaccine storage practice in Ethiopia [28,43,47], but less than Ethiopia [35,36] and India [11]. The difference might be due to a shortage of refrigerators, workloads, poor knowledge, attitudes, and negligence of professionals. Laboratory reagents, anti-rabies vaccines, and maternity medicines were placed with EPI vaccines in 18.5% of health facilities. This was in line with studies conducted in Ethiopia [35,43,47], Cameroon [37], Mozambique [52] and Nigeria [39]. This might be strongly related to cold chain breaks, limited storage space, poor attitude and negligence of professionals. Key informants also mentioned that drugs, water and collected laboratory samples were stored with vaccines in the same refrigerators.

The results of the present study showed that 63% of health centers had good cold chain practices. This finding was better than studies done by Rao et al. and Agueh et al, in which the practice of cold chain was suboptimal [11,27,54] and Ogboghodo et al. and Krishnappa et al. where the practice was fair [34,55]. Breaks in the chain are more frequent and compromise potency [55]. Inefficient vaccine management systems, including poor stock management, poor quality of vaccine handling and storage, to contribute high wastage [40] and these results in revaccination and financial loss [7]. Thus, effective management and storage of vaccines can save program costs, prevent high wastage rates and stock outs, and improve the safety of immunization [41].

An in depth understanding of health facilities cold chain infrastructure and practice will have an implication to avail cold chain equipment for effective management of the vaccine cold chain system in health facilities to the improve immunization supply chain.

Conclusion

The availability of cold chain equipment in health facilities was below average and the practice of cold chain management in health facilities was average. Placement of vaccines during immunization session, checking the signs of damage, storage of food or any drugs other than vaccines, checking thermometer twice daily and updating temperature record sheet, availability of deep freezer, cold box and functional thermometer was significantly associated with vaccine storage. Improving the availability of the cold chain equipment and undertaking regular support and follow up are recommended to improve vaccination services. Key informants stated that cold chain infrastructure, temperature monitoring, stock management and immunization practice affect vaccine storage.

Ethical Considerations

The study was approved by the Ethics Review Committee of the College of Medicine and Health Science, Wollo

University (406/13/11) and Oromia Special Zone Health Department. Consent was also requested from the surveyed health facilities and their respective Woreda health offices. Moreover, study participants involved in the study were fully informed about the nature and objectives of the study and the confidentiality of the data. Then, verbal consent to participate in the study was obtained.

Competing Interest

The authors declare that they have no potential competing interests.

Authors`Contribution

SAM made the analysis. All authors (SAM, BDW and MHK) interpreted the findings and wrote the manuscript. Finally, all the authors proofread and approved the final version of this manuscript.

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Availability of Data and Materials

All relevant data are within the manuscript

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