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Article

Management of Vaccine Cold Chain Equipment in the Ethiopian Immunization Supply Chain System: Evidence from Ethiopian National Immunization Program Evaluation

Yimer Seid Yimer ^{1,*}, Meaza Gezu Shentema ², Awgichew Kifle Zemelak ¹, Mulgeta Tamire ², Ephrem Biruk ¹, Berhanu Fikadie Endehabtu ^{3,4}, Kassahun Alemu ^{3,4}, Binyam Tilahun. ^{3,4}, Admas Abera ⁵, Keneni Gutema Negeri ⁶, Muluemebet Abera Wordofa ⁷, Tekalign Admasu ⁸, Sileshi Solomon ⁸, Melkamu Ayalew ⁸, Meseret Zelalem ⁸, Mesoud Mohammed ⁹ and Girma Taye Aweke ¹

- ¹ Department of Epidemiology and Biostatistics, School of Public Health, Addis Ababa University, Addis Ababa, Ethiopia
- ² Department of Preventive Medicine, School Public Health, Addis Ababa University, Addis Ababa, Ethiopia
- ³ Institute of Public Health, College of Medicine and Health Sciences, University of Gondar, Gondar, Ethiopia
- ⁴ Center for Digital Health and Implementation Science (CDHi), University of Gondar, Gondar, Ethiopia
- ⁵ School of Public Health, Haramaya University, Harar, Ethiopia
- ⁶ School of Public Health, Health Systems Management and Policy Unit, College of Medicine and Health Sciences, Hawassa University
- ⁷ Department of Population and Family Health, Public Health Faculty, Institute of Health Jimma University, Ethiopia
- ⁸ Maternal, Child and Reproductive Health Lead Executive Office, Ministry of Health, Addis Ababa, Ethiopia
- ⁹ Strategic Affairs, Ministry of Health, Addis Ababa, Ethiopia
- * Correspondence: yimer.seid@aau.edu.et or yimer0505@gmail.com; Tel: +251911730505

Abstract

Background: There is insufficient evidence on the current condition of vaccine cold chain equipment (CCE) in Ethiopia. This study is aimed to assess the status of the CCE of the Ethiopian immunization supply chain (ISC) system. **Methods:** A cross-sectional study was conducted at 302 ISC sites across nine regions in Ethiopia using the World Health Organization (WHO) Expanded Program of Immunization (EPI) review guide and the EVM2.0 tool. Data were collected through direct observation and face-to-face interviews with the EVM Assessor mobile app, assessing vaccine storage capacity, including CCE type, brand, and model, at one EPSS center and 15 hubs. **Results:** All EPSS hubs use passive storage devices and have refrigeration and/or freezer units. A total of 408 refrigerators and/or freezers were found at lower distribution (LD) and service provision (SP) levels, including 335 regular refrigerators and 73 combined units (refrigerators and freezers). During the survey, 157 of these refrigerators had a functioning 30-day-temperature-record (30DTR) system. The average storage capacity for vaccines positive (2--8°) was 1434 liters in 286 facilities. The average storage capacity of vaccine negatives (-25--15°) was 538 liters in 286 facilities. The EPSS center and 13 hubs have conducted preventive maintenance and repaired refrigerators in the past year. Most institutions (82.95%) at the LD and SP levels lack a documented preventive maintenance schedule. Only 20% of institutions maintain records of preventive maintenance. **Conclusion:** Improving cold chain management through better temperature monitoring, increased refrigeration, and enhanced transportation is essential to ensure vaccine potency and reduce wastage.

Keywords: cold chain equipment; vaccine supply chain system; EVM2.0; EPI evaluation; Ethiopia

Background

Vaccines are sensitive health commodities that require an efficient supply chain, including storage and transportation systems to maintain the recommended temperature range. The success of immunization activities relies on having sufficient, functioning cold chain equipment (CCEs) to preserve vaccine quality. Immunization supply chain (ISC) management ensures vaccines are stored, transported, and distributed effectively, maintaining potency, minimizing wastage, and maximizing coverage to protect against vaccine-preventable diseases (VPDs) [1]. Immunization supply chain management ensures vaccines are safely delivered to targets on time, maintaining their safety and efficacy through proper handling and temperature control. Efficient supply chains are vital for improving coverage, enhancing vaccine quality, and reducing child morbidity and mortality [2].

The vaccine cold chain is not only an integral part but also the backbone of an immunization program. It is a system for storing and transporting vaccines at recommended temperatures from the point of manufacture to the point of use, thus ensuring the potency and safety of vaccines throughout the transport and storage phases [1]. The “cold life” of a vaccine refers to the period during which the vaccine remains effective and safe to use when it is stored at recommended temperatures. At the EPSS center and hubs, most vaccines are stored at temperatures between 2°C and 8°C (36°F and 46°F), while some vaccines, such as the polio vaccine, can be stored in a freezer at temperatures between -50°C and -15°C (-58°F and 5°F), and other vaccines, such as some COVID-19 vaccines, require ultracold storage at temperatures between -90°C and -60°C (-130°F and -76°F). At lower distribution and service provision levels, all vaccines are expected to be stored at temperatures between 2°C and 8°C (36°F and 46°F) [3].

Cold chain equipment (CCE) includes devices like refrigerators, freezers, cold boxes, and temperature monitors used to store and transport vaccines at the required low temperatures. Effective CCE management involves tracking equipment, scheduling maintenance, planning replacements, and preparing for emergencies. Preventive maintenance prevents failures, while repairs fix breakdowns. Replacement planning ensures continuity, and emergency planning addresses disruptions, such as power loss, with backup equipment and monitoring systems [3].

Health facilities are required to monitor and log vaccine temperatures at least twice a day, including on weekends and holidays, to enable prompt action. Additionally, they should use standard refrigerators and WHO PQS-certified temperature monitoring devices, such as fridge tags and remote temperature monitoring devices (RTMDs), to ensure the cold chain remains intact during storage and transportation [4]. The major challenges of vaccination programs are associated with vaccine cold chain management and cold storage facilities; thus, vaccine cold chain management practices constitute the backbone of successful immunization programs [5].

According to the National cold chain equipment inventory (CCEI) conducted in Ethiopia in 2020 from the total of 20,765 equipment inventoried, 13,170 (63.4%) were functional, 6204 (29.9%) nonfunctional due to variety of reasons, 836 (4.0%) obsolete and 555 (2.7%) uninstalled. Reasons for the non-functionality of the equipment include power (27.9%) [1]. A study conducted in 136 HFs in the Wolaita Zone, Ethiopia, indicated that 133 (97.8%) health facilities had functional vaccine refrigerators in facilities, 108 (79.4%) had a cold box, 107 (78.7%) had ice packs, and 133 (97.8%) had vaccine carriers. Fifty-nine (43.4%) of the health facilities use a refrigerator tag for temperature monitoring in the facility, whereas 77 (56.6%) use a thermometer for temperature monitoring [6]. A similar study conducted in the Gojam Zone of the Amhara region revealed that among 60 health institutions, only 46 (76.7%) had functional refrigerators. Twenty-one (35%) had a functional generator for backup service, and 28 (46.6%) had a car/motorbike for the transportation of vaccines in the case of refrigerator/power failure. The findings of this study also revealed that 35 (58.3%) had appropriate vaccine cold chain management practices. A quality assessment of cold chain storage in a developing country found that 66.7% of facilities failed to meet required standards for cold chain products. Additionally, 50.4% of retail and hospital pharmacies had poor cold chain management practices. Most facilities (66.7%) lacked calibrated equipment, 43.6% had no automated backup for

power failures, and 37.6% didn't perform temperature checks on cold chain products upon receipt [7].

Some factors contributing to weaknesses of the cold chain are delays during transportation, quality of refrigerators, a method of storage, excessive storage at the health unit, improper use of refrigerators, power interruption, equipment breakage, and lack of trained personnel capable of managing the cold chain [8].

The poor performance of cold chain equipment in Ethiopia may contribute to both low vaccination coverage and high vaccine wastage. An umbrella review of five systematic reviews and meta-analyses revealed that the overall rate of full vaccination coverage in Ethiopia was 57.72% (95% CI 50.17, 65.28)[9], falling short of the 75% national target for full (basic) immunization coverage set for 2025 [10]. Additionally, another study indicated that the vaccine wastage rate in public health facilities of the Oromia Special Zone, Ethiopia, was 22.9% [11].

The Ministry of Health-Ethiopia (MOH-E) conducted an Effective Vaccine Management Assessment (EVMA) in 2019 [1] to evaluate the cold chain system, but the assessment is now outdated and lacks evidence for informed decision-making. Ethiopia's cold chain infrastructure faces increased demand due to factors like population growth, expanded health services, rising immunization coverage, and new vaccines. While plans for expanding and replacing cold chain equipment (CCE) [1] are in place, there is a lack of up-to-date data to assess whether existing equipment can meet the demands of the growing immunization program. Ethiopia's cold chain system needs regular rehabilitation and expansion to meet the growing demands of the immunization program. Using the latest evidence, cold chain management can ensure vaccine safety, potency, and cost efficiency. The need to replace aging and nonfunctional equipment highlights the importance of an updated assessment of the current cold chain status. This study aims to fill this gap by evaluating the state of cold chain equipment in Ethiopia, providing data for informed decision-making and effective planning in the Immunization Supply Chain System.

Study Settings

This is a nationwide evaluation carried out at various stages of the immunization supply chain, ranging from the national level to the subnational level, including lower DPs and service delivery facilities. The assessment spans nine regions in Ethiopia: Oromia, Amhara, Addis Ababa, Somali, Sidama, Gambella, Dire Dawa, Benshangul Gumuz, and the former SNNP region. There was one EPSS center and 19 EPSS hubs serving the whole nation related to the immunization supply chain.

Study Design

A facility-based descriptive cross-sectional study that used the WHO EPI review guide [12] and effective vaccine management (EVM2.0) tool [13] was employed to collect data on cold chain equipment and its management.

Target and Study Population

The target population may include all Immunization Supply Chain (iSC) points or facilities, such as those involved in storing, distributing, or delivering immunization services. However, the study population consisted of active Immunization Supply Chain (iSC) points or facilities that store, distribute, or provide immunization services within the chosen districts and EAs.

Sample Size and

The iSC facilities were selected from 505 enumeration areas (EAs) (127 EAs from urban areas and 378 EAs from rural areas). EAs were allocated to urban and rural strata on the basis of the proportion of the national population living in urban and rural areas (21.4% urban and 78.6% rural). If the selected EAs have no facility storing and/or distributing and/or providing immunization services, a facility in the chain of the EPI referral link from neighboring EAs was considered for the

iSC assessment. Accordingly, the EPSS center, 15 EPSS hubs and 286 facilities at the lower distribution and service provision level were involved in this study. Facilities were selected from 23,255 total active iSC points via the EVM assessment site selection and sampling tool, assuming a 90% confidence level and 10% precision [14].

Sampling Procedure

The facilities were chosen randomly, as the selected EAs were randomly spread across the country. A facility was included if it was involved in storing, distributing, or providing immunization services

Data Collection

Data were collected via observation, inspection of infrastructure and records, and face-to-face interviews with staff via the EVM Assessor mobile app [13] by trained and experienced data collectors selected from local universities and the EPSS. We have utilized the EVM Assessor, as it is the current standard tool for conducting Effective Vaccine Management (EVM) evaluations, which includes the management of vaccine CCEs. We observed the labeling or packaging on the refrigerator-freezers to document the net storage capacity of the vaccine cold chain equipment (CCEs). Additionally, the EVM assistant tool [15] was utilized to calculate vaccine storage capacity by noting the type, brand, and model of the CCEs. Data collectors and supervisors were trained for two days on data collection tools and procedures and the application of the EVM tool before deployment. Pretesting was carried out outside the sampled facilities. Approximately five questionnaires were completed at each pretest facility. The pretest was used to check the clarity of each question, identify ambiguous questions, and check skipping patterns and the flow of questions.

Data Management and Analysis

The EVM data were imported into Excel for extracting and cleaning variables related to CCE, then exported to STATA for analysis [16]. A descriptive analysis was performed, with continuous variables summarized as means and standard deviations, and categorical variables presented as counts and percentages.

Results

Profile of Study Setting

The assessment covered one primary store (EPSS center) and 15 subnational stores (EPSS hubs). The EPSS hubs were geographically distributed across various Ethiopian regions, including four in Oromia, three in Amhara, two in Addis Ababa, and one each in Somali, Sidama, Gambella, Dire Dawa, Benishangul Gumuz, and former SNNP. At the lowest distribution (LD) level (Woreda) and service provision (SP) points, 286 institutions were assessed. These included 101 (35.3%) health centers (HC), 90 (31.4%) Woreda Health Offices (WorHO), 83 (29%) health posts (HP), and the remaining 12 (4.2%) hospitals. The majority of institutions were from Oromia, 85 (29.7%) and Amhara, 52 (18%), followed by SNNP, 34 (11.8%). Five HCs were assessed in Addis Ababa.

Availability of Cold Chain Equipment (CCE)

All the hubs were equipped with cold rooms and/or freezer rooms. There were 58 cold rooms across all hubs, with three lacking automatic deforestation and 27 missing door-open alarms. The distribution of cold rooms among hubs was as follows: 12 in the EPSS center, 3 hubs had 5 each, 2 hubs had 4 each, 5 hubs had 3 each, 3 hubs had 2 each, 2 hubs had one each, and only 4 had combined units. None of the cold rooms or freezer rooms in the hubs had computerized temperature monitoring (CTM). There were no reported downtime incidents affecting the vaccine supply in the last 12 months.

Every hub had at least one refrigerator or freezer, totaling 38 across national and subnational hubs. The central hub contained 8 refrigerators, while each subnational hub had between one and six refrigerators (Table 1).

Table 1. Cold/freezer rooms at central and subcentral hubs in Ethiopia, 2023.

Variables		EPSS		Total (n=16)
		Center (n=1)	Hub (n=15)	
Facility has any cold rooms and/or freezer rooms	Yes	1	15	16
Cold rooms and/or freezer rooms were well ventilated	Yes	1	15	16
Total number of cold rooms in the hub	12	1	-	1
	5	-	3	3
	4	-	2	2
	3	-	5	5
	2	-	3	3
	1	-	2	2
	0	-	1	1
Number of cold rooms with automatic deforestation	12	1	-	1
	5	-	2	2
	4	-	3	3
	3	-	5	5
	2	-	2	2
	1	-	2	2
	0	-	1	1
Number of cold/freezer rooms with a door-open alarm	6	-	1	1
	5	-	1	1
	4	-	2	2
	3	-	2	2
	2	-	2	2
	1	1	2	3
	0	-	5	5
Total number of refrigerators	8	-	1	1
	6	1	-	1
	4	-	1	1
	3	-	4	4
	2	-	3	3
	1	-	2	2
	0	-	4	4
Total number of combined refrigerator-freezers	0	1	11	12
	1	-	2	2
	2	-	1	1
	3	-	1	1
Number of refrigerators with a functional 30-Day Temperature Record (30DTR)	0	1	11	12
	1	-	1	1
	2	-	2	2
	3	-	1	1
Refrigerators/freezers equipped with a Computerized temperature Monitoring system	No	1	15	16
Downtime incidents that affected the supply During the past 12 months	No	1	15	16

Table 2 shows the availability of cold chain equipment at a lower distribution and service provision level by facility type: A total of 335 refrigerators are available at lower distribution and service provision levels. Seventy (24.5%) institutions had no refrigerator, including 15 (15%) health centers, 30 (36%) health posts, 1 (8.3%) hospital, and 24 (26.7%) lower distribution points. The maximum number of refrigerators owned by the institutions is four, which are found in 7 lower distribution centers and 4 HCs. One refrigerator is commonly available in the store in 133 institutions, and two are available in 58 institutions. A considerable proportion (46.5%) have just one, whereas the majority have one or two (66.8%). A total of 174 institutions (61%) owns 157 refrigerators with a functional 30-day temperature record (30DTR), but each has a varying number of refrigerators, ranging from one to three. On the other hand, the total number of combined refrigerators and freezers in these institutions is 73. There were no combined refrigerator-freezers in the stores of 227 institutions and only one in 46. Of the 408 refrigerators (including refrigerator-freezer combinations) assessed, 397 (97%) were in good condition for temperature control.

There were 40 refrigerators/freezers with a computerized temperature monitoring system at the LD and SP levels. The majority of the institutions 227 (88%) did not have refrigerators/freezers with a computerized temperature monitoring system. At a lower distribution and service provision level, of the 30 health institutions with CTMS, 83% reported that the CTMS displayed temperature trends. Specifically, 92% of the HCs, 33% of the HPs, 100% of the hospitals, and 85% of the lower distribution centers reported that their CTMS values displayed temperature trends. In the past 12 months, 25 (10%) institutions, excluding hospitals, reported incidents of downtime that impacted storage conditions.

At the regional level, nearly 55.5% of institutions in Sidama, 35.23% of institutions in SNNP, and 33.3% of institutions in Afar did not have refrigerators in the store. With respect to the availability of combined refrigerator-freezers in the store, only 20% of institutions in all regions have at least one. A total of 72.2% of institutions in Sidama lack functional refrigerators with a 30-day temperature record (30DTR), whereas in SNNP and Southwest Ethiopia, the figures are 58.8% and 55.5%, respectively. All the institutions across the regions have very few refrigerators with proper temperature control. None of the refrigerators were functional in 50% of Sidama’s institutions, 23.5% in SNNP, or 22.2% in Southwest Ethiopia. Additionally, all health institutions in Amhara, Dire Dawa, Harari, and Sidama lack refrigerators or freezers with computerized temperature monitoring systems (CTMS) (Supplementary file 1).

Table 2. Cold chain equipment and temperature management by facilities at lower distribution and service provision levels by health institution type in Ethiopia, 2023.

		Health Institution type				
		Health Center (n=101)%	Health Post (n=83)%	Hospital (n=12)%	Lower distribution (n=90)%	Total (n=286)%
Total number of refrigerators	0	15 (14.9)	30 (36.1)	1 (8.3)	24 (26.7)	70 (24.5)
	1	47 (46.5)	47 (56.6)	8 (66.7)	31 (34.4)	133 (46.5)
	2	28 (27.7)	6 (7.2)	3 (25.0)	21 (23.3)	58 (20.3)
	3	7 (6.9)	0 (0.0)	0 (0.0)	7 (7.8)	14 (4.9)
	4	4 (3.9)	0 (0.0)	0 (0.0)	7 (7.8)	11 (3.8)
Total number of combined refrigerator-freezers	0	71 (70.3)	73 (87.9)	11 (91.7)	72 (80.0)	227 (79.4)
	1	23 (22.8)	10 (12.1)	1 (8.3)	12 (13.3)	46 (16.1)
	2	7 (6.9)	0 (0.0)	0 (0.0)	5 (5.5)	12 (4.2)
	3	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	1 (0.4)
Number of refrigerators with a functional 30-Day Temperature Record	0	23 (22.8)	56 (67.5)	4 (33.3)	29 (32.2)	112 (39.2)
	1	53 (52.5)	26 (31.3)	7 (58.3)	38 (42.2)	124 (43.4)
	2	20 (19.8)	1 (1.2)	1 (8.3)	17 (18.9)	39 (13.6)
	3	5 (4.9)	0 (0.0)	0 (0.0)	6 (6.7)	11 (3.8)

(30DTR						
Number of refrigerators with good functional status regarding temperature control	0	6 (5.9)	21 (25.3)	1 (8.3)	15 (16.7)	43 (15.0)
	1	43 (42.6)	57 (68.7)	8 (66.7)	31 (34.4)	139 (48.6)
	2	34 (33.6)	5 (6.0)	3 (25.0)	25 (27.8)	67 (23.4)
	3	13 (12.9)	0 (0.0)	0 (0.0)	11 (12.2)	24 (8.4)
	4	5 (4.9)	0 (0.0)	0(0.0)	8 (8.9)	13 (4.5)
Number of refrigerators/freezers with a Computerized Temperature Monitoring System	0	89 (88)	61(94)	10(83)	67(85)	227 (88)
	1	9 (9)	4 (6)	2 (17)	7 (9)	22 (9)
	2	3 (3)	0 (0)	0 (0)	3 (4)	6 (2)
	3	0 (0)	0 (0)	0 (0)	2 (3)	2 (1)
Computerized Temperature Monitoring System (CTMS) display temperature trends	Yes	11 (92)	1(33)	2 (100)	11(85)	25 (83)
Downtime incidents affecting storage conditions during last 12 months	Yes	8 (8)	6(9)	0(0)	11(14)	25(10)

Power Infrastructure at the Central and Sub-Central Hubs

All 16 hubs had their supply chain equipment connected to electricity, except for one hub, which only had power for 8 hours a day. None of the hubs used onsite solar power for their cold chain equipment. While all 16 hubs were equipped with electricity generators, one of these generators was not functional. Over the past 12 months, six of the 15 sub-central hubs reported power outages lasting more than 4 hours.

Power Infrastructure at the Lower Distribution (LD) and and Service Provision Level (SP)

Table 3 presents various electricity-related characteristics of health facilities across different categories (Health Center, Health Post, Hospital, and Lower Distribution). Less than half of the facilities (48%) have cold chain equipment connected to electricity. Most Hospitals (66%), Health Centers (65%) and Lower Distribution facilities (65%) have cold chain equipment connected to electricity, while fewer Health Posts (5%) have it. Overall, 81.6% of the facilities receive electricity for 24 hours a day. The majority of Health Centers (82%) and all Health Posts (100%) and Hospitals (100%) receive 24 hours of electricity per day. Lower Distribution facilities receive 77.5% of their electricity for 24 hours. 93.7% of the facilities experienced power cuts of more than 4 hours. A large proportion of Lower Distribution (97.8%), Health Centers (89.7%), and Hospitals (6%) experienced power cuts of more than 4 hours. Out of 286 facilities, 37% do not have cold chain equipment powered by a solar system. A large percentage of Health Centers (30.7%) and Hospitals (66.7%) have cold chain equipment not powered by solar systems. In Lower Distribution, 67% of the equipment is not powered by solar. 67% of the facilities do not have electricity generators as a power source for cold chain equipment. Health Posts have the highest percentage without an electricity generator (97.6%), followed by Lower Distribution (71%). Health Centers (44.6%) and Hospitals (16.7%). A notable percentage of generators at Health Centers (25%) and Lower Distribution (17%) are not functional at the time of this evaluation. The majority of Health Centers (66%) and Lower Distribution (71%) have generators that are working well, with the highest percentage found in Hospitals (90%).

Table 3. Electric power related characteristics of health facilities across different categories.

		Health Center n(%)	Health Post n(%)	Hospital n(%)	Lower distribution n(%)	Total
Cold chain equipment in the facility connected to an electricity	No	35 (35)	78 (95)	4 (33)	31(35)	148 (52)
	Yes	66 (65)	4 (5)	8 (66)	58 (65)	136 (48)
	Total	101	82	12	89	284
Hours of grid electricity the facility receive per day	24	54 (82)	4 (100)	8 (100)	45 (77.5)	111 (81.6)
	20	1 (1.5)	0 (0)	0 (0)	2 (3.4)	3 (2.2)
	17	1 (1.5)	0 (0)	0 (0)	1 (1.7)	2 (1.4)
	16	3 (4.5)	0 (0)	0 (0)	1 (1.7)	4 (3)
	15	1 (1.5)	0 (0)	0 (0)	0 (0)	1(0.7)
	12	3 (4.5)	0 (0)	0 (0)	2 (3.4)	5 (3.6)
	10	1 (1.5)	0 (0)	0 (0)	1 (1.7)	2 (1.4)
	8	0 (0)	0 (0)	0 (0)	4 (6.8)	4 (3)
	6	1 (1.5)	0 (0)	0 (0)	1 (1.7)	2 (1.4)
	4	1 (1.5)	0 (0)	0 (0)	1 (1.7)	2 (1.4)
	Total	66	4	8	58	136
Power cuts of more than 4 hours in the past 12 months	No	6 (10.3)	0 (0)	0 (0)	1 (2.2)	7 (6.3)
	Yes	52 (89.7)	3 (3)	6 (6)	44 (97.8)	105 (93.7)
	Total	58	3	6	45	112
On-site solar power system for cold chain equipment	No	31 (30.7)	4 (6)	8 (66.7)	53 (67)	96 (37)
	Yes	70 (69.3)	62 (94)	4 (33.3)	26 (33)	162 (63)
	Total	101	66	12	79	258
Availability of electricity generator	No	45 (44.6)	81 (97.6)	2 (16.7)	64 (71)	192 (67)
	Yes	56 (55.4)	2 (2.4)	10 (83.3)	26 (29)	94 (33)
	Total	101	83	12	90	286
Functional status of generator	Not working	14 (25)	2 (100)	1 (10)	4 (17)	21 (22.8)
	Working but needs repair	5 (9)	0 (0)	0 (0)	3 (12)	8 (8.7)
	Working well	37 (66)	0 (0)	9 (90)	17 (71)	63 (68.5)
	Total	56	2	10	24	92

Management of Vehicle Cold Chain Equipment at the EPSS Center and Hubs

The EPSS center has two refrigerated vehicles, each equipped with temperature-monitoring units in the driver’s cabin. Eight hubs do not have refrigerated vehicles, whereas seven hubs have one refrigerated vehicle each; only two hubs have functional 30-day temperature records (30DTR). Two refrigerated vehicles had a functional temperature monitoring unit. There were 83 vehicles equipped with a geographic location transmitter, 52 of which were working for the EPSS central hub (Table 4).

Table 4. Temperature management of vehicles at the EPSS center and hubs in Ethiopia, 2023.

Variables		EPSS		Total (n=16)
		Center (n=1)	Hub (n=15)	
Total number of refrigerated vehicles	2	1	-	1

	1	-	7	7
	0	-	8	8
Number of vehicles with a Temperature monitoring unit in the driver's cabin	2	1	-	1
	1	-	6	6
	0	-	1	1
Number of vehicles with a functional temperature monitoring unit	2	1	-	1
	1	-	4	4
	0	-	2	2
Number of vehicles with a functional 30-Day Temperature Record (30DTR)	Yes	-	2	2
	No	1	5	6
Number of vehicles equipped with a geographic location transmitter	52	1	-	1
	8	-	1	1
	5	-	1	1
	4	-	2	2
	2	-	1	1
	1	-	8	8
	0	-	1	1

Storage Capacity of CCEs at the EPSS Center and Hubs

Table 5 presents the cold room and refrigerator storage capacities at the EPSS center and hubs. Accordingly, in the EPSS central hub, the overall storage capacity for vaccines requiring a positive temperature (2–8 degrees Celsius) was 440,768 liters, whereas for those needing a negative temperature (-25--15 degrees Celsius), it was 40,000 liters. Across the 15 hubs, the average storage capacity for positive-temperature vaccines was 51,953 liters (with a standard deviation of 38,666 liters), and for negative-temperature vaccines, the average was 1,980 liters (with a standard deviation of 3,504 liters). The net storage capacity of cold rooms in the EPSS Center is 441 m³, whereas it is 40 m³ for freezer compartments. The hubs' cold rooms scored 798 m³, with a mean (SD) of 53 (37) m³. Only four hubs had freezer compartments in their cold rooms, with an aggregate capacity of 12 m³. Nine hubs have a total net capacity of 2430 liters of refrigerators; thirteen hubs have a total net vaccine storage freezer capacity of 13930 liters. The total transportation capacity of the CHs' refrigerated vehicles was 41 m³, whereas nine hubs had a total capacity of 85.3 m³ (mean (SD): 17.1 (11.2) m³). Nonrefrigerated vehicles at the central hub cover 1746 m³, whereas those at the nine hubs cover 1004.1 m³ (mean (SD): 111.6 (76.6) m³). The CH possesses a net storage capacity of 1969.8 liters in insulated containers, whereas hubs average 763.6 liters (mean (SD): 63.6 (27.6)). The CH had a net storage capacity of 1969 liters in an insulated container. The means (SDs) of the gross and net storage capacities of the dry goods in the 15 hubs were 1665 (3762) and 1157 (2665) liters, respectively. The mean (SD) net storage capacity of the insulated container in the 12 hubs was 63 (27) liters.

Table 5. Storage capacity of cold rooms, refrigerators/freezers, dry storage areas, and insulated containers at the central and subcentral EPSS hubs.

Variable	Center n=1	Hub		
		n	Total	Mean (SD)
Cold rooms storage capacity in m³				
Gross storage capacity of the refrigerator compartment	2249	15	2224	148 (69)
Net storage capacity of the refrigerator compartment	441	15	798	53 (37)
Gross storage capacity of the freezer compartment	201	4	72	18 (3)
Net storage capacity of the freezer compartment	40	4	12	3 (1)
Refrigerator/freezer storage capacity in liters				

Net vaccine storage capacity of the refrigerator	-	9	2430	405 (278)
Net vaccine storage capacity of the freezer	-	13	13,930	1071 (401)
Net cool water-pack storage capacity of the refrigerator	600	8	3613	451 (252)
Net ice-pack storage capacity of the freezer	435	13	11,404	877 (565)
Total storage capacity: Cool packs	44,677	13	37,555	2888 (1627)
Total storage capacity: Icepacks	40,000	13	25,743	1980 (557)
Total storage capacity: Coolant packs	4435	15	12,501	961 (3403)
Net storage capacity of the insulated container	1969	12	763	63 (27)
Total storage capacity: Vaccines, positive	44,0768	15	779,304	51,953 (38666)
Total storage capacity: Vaccines, negative	40,000	13	25743	1980 (3504)

Storage Capacity of CCEs at the Lower Distribution and Service Provision Level

The average (SD) storage capacity for vaccine positive vaccines (2–8 degrees Celsius) was 1434 (11243) liters in 286 facilities. The average (SD) storage capacity of vaccine negatives (-25 to -15 degrees Celsius) was 538 (5732) liters in 286 facilities. The average (SD) storage capacities for cool-packs, ice-packs, and coolant packs were 593 (7580), 141 (1446), and 733 (8913), respectively, for these facilities. The average net vaccine storage capacity of refrigerators in 254 institutions was 176 liters. The average net storage capacities of the cool water pack of the refrigerators and the icepacks of the freezers were 16 and 12 liters, respectively. Freezers had an average net vaccine storage capacity of 16 liters (n=253). The average (n=286) net storage capacity of insulated containers was 16 liters (Table 6).

Table 6. Storage capacity of refrigerator/freezer and insulated containers at the LD and SP levels.

	Overall		Health Centre		Health Post		Hospital		Lower distribution	
Capacity (Lit.)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
Total storage capacity: Vaccines, positive	286	1434(11243)	101	1418 (9932)	83	22 (34)	12	8481 (28856)	90	1814 (13503)
Total storage capacity: Vaccines, negative	286	538 (5732)	101	230.5 (1997)	83	1.5 ()	12	3.6 (12.4)	90	1450 (9974)
Net vaccine storage capacity of the refrigerator	254	176 (1253)	99	298 (2003)	65	26 (34)	12	143 (52)	78	152 (109)
Net cool water-pack storage capacity of the	254	16 (50)	99	22 (61)	65	*	12	20 (47)	78	22 (55)

refrigerator										
Net ice-pack storage capacity of the freezer	253	12 (44)	99	13 (43)	64	2 (7)	12	*	78	20 (61)
Net vaccine storage capacity of the freezer	253	16 (57)	99	13 (42)	64	2 (7)	12	4 (12)	78	34 (88)
Total storage capacity: Cool-packs	286	592.6 (7580.3)	101	1385 (12608)	83	0.0	12	20 (47)	90	326 (2055)
Total storage capacity: Ice-packs	286	140.8 (1445.8)	101	255 (2245)	83	1.4 (6)	12	0.0 (0.0)	90	159.6 (998)
Total storage capacity: Coolant packs	286	733(8913)	101	1641(14843)	83	1.4 (6.2)	12	20.0 (47)	90	485.5 (2299)
Total net storage capacity of all the insulated containers	286	16 (57)	101	19 (77)	83	6 (10)	12	9 (10)	90	22 (60)
*the information is missing										

Maintenance & Repair of Cold Chain Equipment

The EPSS center and 13 hubs have conducted preventive maintenance and repaired refrigerators in the past year. The central hub maintains the facility’s refrigeration equipment by themselves and NGOs. The refrigeration equipment of the hub facility was maintained by NGOs (3 hubs), Governmental & NGOs (2 hubs), the facility itself (2 hubs), Facility and NGOs (4 hubs), Facility and Governmental organizations (1 hub), and Facility/Governmental and NGOs (3 hubs).

The majority of institutions, 214 (83%), lacked a documented plan/schedule for preventive maintenance of refrigeration equipment (n=258). The availability of such a plan/schedule varied by type of health institution, with health posts having the highest percentage (96%) without a schedule, followed by health centers (86%), lower distribution points (71%), and hospitals (67%). Among the 258 institutions, 207 (80.23%) reported no repairs to refrigeration equipment in the past 12 months. Repair services differed among institutions, with most HCs (87%) and HPs (91%) not having any repair services. Only seven (20%) institutions kept records of preventive maintenance work (n=35). The percentage of those with records varied by type, ranging from 11% for HCs to 50% for hospitals.

Discussion

According to the WHO, the recommended temperature range for most vaccines is between 2°C and 8°C [17]. If the temperature deviates from this range, the potency and effectiveness of the vaccines may decrease, leading to reduced protection and an increased risk of vaccine-preventable diseases. Therefore, ensuring that all institutions have sufficient and functional cold chain equipment to store vaccines and monitor their temperature regularly is essential.

The research revealed that all hubs were equipped with cold rooms and/or freezer rooms. However, many cold rooms lack automatic defrosting and door-open alarms, and none of the refrigerators perform computerized temperature monitoring. Despite these shortcomings, there have been no reported disruptions in vaccine supply over the past year. This could be because cold rooms at EPSS hubs have remote temperature monitoring devices that are capable of sending alarms when doors open. Addressing the deficiencies of passive storage devices could help keep life-saving vaccines at appropriate temperatures for one month or more without the need for electricity, which is critical in the local context where there is no reliable electric supply. The 2020 Ethiopian National Cold Chain Equipment Inventory (CCEI) [1] revealed significant gaps in equipment functionality, where the number of refrigerators with good functional status was 15%, which is better than the previous finding, where 29.9% of the total 20,765 pieces of equipment inventoried were nonfunctional and 4.0% were obsolete.

This research highlights a significant disparity in the availability and adequacy of refrigeration equipment across health facilities. Only 335 refrigerators are available at lower distribution and service provision levels, whereas 82% of institutions have refrigerators with functional 30-day temperature records, 46% of facilities have only one refrigerator and a lack of combined refrigerator-freezers. This may be reasonable since the majority of facilities at lower distribution and service provision levels need only one refrigerator, and some HFs may have a combined refrigerator/freezer type. This finding contrasts with the WHO recommendation that each facility should have at least two refrigerators and one combined refrigerator-freezer [1].

Interestingly, our findings showed that 97% of refrigerators function well underscore a general adequacy in operational status but reveal a need for increased supply and distribution of cold chain equipment, particularly in regions with low functional cold chain equipment. This finding is much better than that of a study conducted among 60 health institutions in the East Gojam zone of the Amhara region [8], where only 46 (76.7%) had functional refrigerators.

Research indicates that only 20% of institutions have combined refrigerator-freezers, which are essential for the preparation of cool water packs. The lack of this equipment limits the capacity to maintain the temperature of vaccines through cool water packs, potentially affecting their availability and accessibility, particularly in remote and rural areas where immunization needs are critical. Increasing the number of combined refrigerator-freezers could enhance vaccine storage capabilities and improve immunization services in underserved regions [4].

This research underscores significant challenges in vaccine management due to inadequate temperature control during transportation and storage. While the EPSS center has two refrigerated vehicles with temperature-monitoring units, regional facilities have considerable deficiencies. A study conducted in India reported that 4.7% of CCEs did not have a temperature monitoring device [18]. According to this study, many regions in Ethiopia lack functional refrigerators with essential 30-day temperature records (30DTR) and computerized temperature monitoring systems (CTMS). To mitigate these issues, there is a need for improved temperature monitoring and more reliable refrigeration equipment across all health institutions. Regular temperature checks and upgrades to equipment could enhance vaccine preservation and reduce waste.

Our findings reveal significant variability in vaccine storage capacity and highlight gaps that could impact effective vaccine management. The EPSS center has a substantial total storage capacity of 480.8 m³, which is inadequate compared with the 756 m³ total storage capacity needed to receive all doses at one time at the EPSS Center [1,4]. In contrast, the hubs had a higher total storage capacity of 805 m³ than the total storage capacity of 784.9 m³ needed to receive all doses at one time at the EPSS

hubs [1,4]. This finding is supported by a study conducted at the Jimma EPSS hub [19], which revealed that branches have sufficient positive storage capacity, but the available negative storage volume covers only 65% of the negative storage capacity needed. The limited freezer space at hubs (11.8 m³) and the overall lower storage capacities for cool-packs and ice-packs in various facilities indicate potential risks in maintaining optimal vaccine temperatures. The average storage capacities for vaccines and cold packs are notably diverse, with some facilities having inadequate space for proper storage and transportation of vaccines. To enhance vaccine management, it is crucial to address these capacity discrepancies by improving storage facilities at both EPSS centers and hubs. Expanding freezer capacity, increasing the availability of refrigerated vehicles, and ensuring that all facilities have adequate cold chain equipment can help minimize the risk of vaccine damage. Proper assessment and upgrading of cold chain infrastructure will ensure better preservation of vaccines and improve overall immunization efficiency.

The findings reveal significant gaps in power availability and reliability for effective functioning of CCEs. While 66% of hospitals, 65% of health centers, and 65% of lower distribution facilities have cold chain equipment connected to electricity, only 5% of health posts do, highlighting a rural infrastructure disparity. Despite 81.6% of facilities having 24-hour electricity, 93.7% experience power cuts lasting over 4 hours, making the cold chain vulnerable. Additionally, 37% of facilities lack solar-powered systems and 67% do not have generators, further weakening backup power solutions. Other studies have reported similar findings, except for health centers, where better access to electricity was observed in our study. A 2021 evaluation of energy access in Ethiopian health facilities revealed that about 90% lack modern energy systems, with 70% of hospitals, 28% of health centers, and 5% of health posts having electricity[20]. Another study found that 63% of facilities use electricity, 37% rely on solar power, and 55.6% have functional generators [21]. Additionally, a study in East Gojam zone reported that 35% of facilities had functional generators for backup power[8]. Ensuring all facilities, particularly in remote areas, have well-maintained generators and solar systems should be a policy priority. Providing incentives for solar and backup power installation can improve the cold chain's reliability.

This research findings reveal critical issues in vaccine management related to cold chain equipment maintenance. Most institutions lack a documented preventive maintenance schedule, with 82.95% of facilities not having one. A significant number of institutions have not conducted any repairs in the past year, and only 20% maintain records of preventive maintenance. Health posts face additional challenges, including the absence of refrigerators and shortages of spare parts and skilled technicians. A similar finding was reported in [18], where there was no planned preventive maintenance of CCEs. Similarly, a study conducted in Kenya reported that the number of facilities that had a routine maintenance plan for CCEs was below average [22]. These deficiencies can lead to delayed repairs and jeopardize vaccine viability, affecting last-mile delivery and overall immunization efforts. Improved documentation, regular maintenance, and better resource allocation are needed to ensure effective vaccine storage and management.

Strength and Limitation of the Study

This study's strength lies in its national coverage of all levels of the immunization supply chain (iSC) in Ethiopia, the application of standard WHO tools, and the direct observation of facilities and cold chain equipment (CCEs) to objectively measure variables. However, there are some limitations. The study was unable to identify factors affecting the management of CCEs within the Ethiopian iSC system.

Conclusions and Recommendations

In conclusion, this research highlights critical deficiencies in the cold chain management of vaccines in Ethiopia, emphasizing the need for functional refrigeration equipment and regular temperature monitoring to maintain vaccine potency. Despite some improvements, such as a majority of refrigerators being operational, significant gaps remain, particularly in the availability of

combined refrigerator-freezers and in the implementation of preventive maintenance schedules. Addressing these shortcomings through increased supply, better monitoring systems, and infrastructure upgrades is essential for effective vaccine management, especially in underserved regions, to ensure that immunization efforts are not compromised. To ensure the ultimate effectiveness of vaccine storage and distribution, it is vital to implement a multifaceted cold chain management strategy that includes upgrading equipment, establishing regular maintenance protocols, and providing comprehensive training for local technicians.

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