Original Article

Assessment of Cold Chain Equipments and Their Management in Government Health Facilities in a District of Delhi: A Cross-Sectional Descriptive Study

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Abstract

Background: Cold chain equipments (CCEs) at health facilities (HFs) are an essential part of the immunization supply chain (ISC). The CCEs in government HFs of Delhi were never assessed using the World Health Organization-United Nations Children's Fund (WHO-UNICEF) Effective Vaccine Management (EVM) tool except that of state vaccine store during National EVM assessment 2013. **Objectives:** The objective of the study was to assess the CCEs and their management in government HFs using the WHO-UNICEF EVM tool in a district of Delhi. **Methods:** The assessment was done during December 2017–March 2018 in one randomly selected district of Delhi. Sample size and site selection were done using the WHO EVM site selection tool. A total of 29 HFs were assessed along with District Vaccine Store. Questions on CCEs in EVM tool 1.0.9 were used for data collection. **Results:** Out of 56 electrical CCEs, 8.9% were nonfunctional, 48.2% were noncompliant with WHO standards, 5.4% were not chlorofluorocarbon free, 4.7% did not have temperature monitoring device, and 18.8% did not have stabilizer. Eighty-six percent of passive containers were compliant with the WHO standards. The storage capacity of electrical vaccine storage equipment was insufficient in 3.4%, passive container capacity in 65.5%, and ice packs preparation and storage capacity in 24.1% of HFs. There was no planned preventive maintenance of CCEs and no standard operating procedures for emergency event management. **Conclusion:** There was a shortage of vaccine storage, ice packs preparation and storage, and passive container capacity. Many CCEs used in ISC of assessed sites were noncompliant to the WHO standards. There was no PPM of CCEs and no guidelines for emergency event management.

Key words: Cold chain equipments, Delhi, effective vaccine management, immunization supply chain

Introduction

Immunization is one of the most cost-effective public health interventions for disease prevention. As per the World Health Organization (WHO), immunization prevents 2–3 million deaths per year globally[1] but there are still 19.4 million unvaccinated and under-vaccinated children in the world[2] and additional 1.5 million deaths can be prevented by improving global immunization coverage.[3] In India, vaccine-preventable diseases cause 0.5 million deaths annually.[4] These facts call for a need for further improvement in immunization. For effective implementation of the immunization program certain key factors such as immunization supply chain (ISC) system needs greater focus. ISC system comprises the people, data, assets, and processes that manage the data collection, forecasting, ordering, distribution, storage, and delivery of vaccines.[5] To improve ISC system in any country, assessment of vaccine and cold chain management are required, as it would help find out different lacunae, identify strong and weak areas and hence layout implementable improvement plans. To set a standard, the WHO and United Nations Children's Fund (UNICEF) together developed a tool in 2001 called as Vaccine Management Assessment Tool.[6] Subsequently, in

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2003, a tool called Effective Vaccine Store Management was developed.[7] Later in 2010, both the tools were integrated together and a new web-based tool called Effective Vaccine Management (EVM) was developed.[8]

Besides well-trained staff and accurate vaccine inventory management an effective cold chain relies on reliable cold chain equipments (CCEs) and temperature monitoring devices.[9] These CCEs include the electrical equipment like cold room/walk-in cooler and freezer room/walk-in Freezer. An ideal cold room should not have any corrosion, all panel joints properly sealed with no signs of excessive condensation or ice build-up on the face of the panels. If there is dual refrigeration unit, there should be a duty sharing system for the dual units, either manual or automatic for periodic changeover. The doors of the cold room or freezer room should have a locking system from outside but should be freely opened from inside. The shelves in the cold room/freezer room should be of good quality so that once the vaccine is loaded on them, there should be no sagging. The cold rooms in cold climate region should have a low-temperature protection circuit. The warm clothing should be available for the workers handling the cold rooms/freezer rooms. Other electrical CCEs include Ice Lined Refrigerators (ILRs) and Deep Freezers: All vaccines refrigerator and freezers should comply with WHO specifications. The ILRs should be fitted with correct vaccine storage basket type. There should be sufficient availability of the daily hours of electricity throughout the year for the installed equipment. To ensure the daily essential electricity supply, backup in the form of generator should be available. The installed generator should have the capacity to support all the connected refrigeration units that are there and should have sufficient capacity fuel tank with adequate reserves for fuel supply. It is recommended that generator should have 72 h continuous running, but this is context dependent. If power cuts are short and/or fuel is readily available, a smaller capacity is acceptable. There should be sufficient availability of kerosene and gas for CCE running on kerosene and gas. Vaccine refrigerator should have low temperature protection circuit in case of cold climates. All the installed refrigeration equipment should be chlorofluorocarbon (CFC) free. All the refrigeration equipment should be connected with voltage stabilizer of the right type especially if there is a voltage fluctuation of ± 15%.[10] Furthermore, there are nonelectrical CCEs/passive containers which include cold boxes and vaccine carriers. Passive containers kept at the facility should comply with WHO specification.[11] EVM Global Data Analysis 2009–2015 by WHO regarding the infrastructure status shows that more than half of the 39 national stores in WHO African region did not meet the EVM quality standard for CCEs.[12] For India, these criteria were 69% as per the National EVM India 2013.[13]

As per information from the National Cold Chain Vaccine Management Resource Centre (NCCVMRC) which is one of the technical resource center to MOHFW for cold chain network in India, the CCEs in government health facilities (HFs) of Delhi have never been assessed using standard EVM tool except those of state vaccine store during the National EVM assessment 2013 (All the EVM assessment conducted so far are available on the website of Immunization Technical Support Unit and National Cold Chain Management Information System. In this context, this study was conducted to assess the CCEs and their management in government HFs using WHO-UNICEF EVM tool in a district of Delhi.

Materials and Methods

Study design and study area

It was a cross-sectional descriptive study conducted in Delhi during December 2017–March 2018. Of the 11 revenue districts in Delhi, one of them was selected by simple random sampling. Selected HFs in the district constituted the study settings.

Sample size and sampling technique

The sampling units for the study were HFs which were storing and maintaining the vaccines in Cold Chain. These are also called Cold Chain Points (CCPs). All of the HFs/CCPs in the selected district were identified (total of 40). The number of HFs/CCPs to be assessed was determined using reference from sample size table available in WHO-UNICEF EVM site selection tool version 1.7.[14] For determining the sample size, 90% confidence interval and 10% precision level was used. For the identification of the HF to be assessed, probability proportional to target population was used as suggested in the WHO-UNICEF EVM site selection tool. The total district population and target population served by the HFs used for site identification was the one which was used by District National Health Mission Office for implementation and reporting under various National Health Programmes. Total sites identified for assessment using the site selection tool were 22. During data collection, it was found that majority of these 22 identified HFs were using the domestic refrigerators for vaccine storage and ice packs preparation. This finding was not as per the WHO specified standards. During the data collection period, it was found that the state government was distributing ILRs to the HFs, so to get a better picture on existing status of CCEs additional 7 HFs were purposively assessed. Hence, a total of 29 out of 40 HFs in the district were assessed. Along with these HFs, District Vaccine Store (DVS) was also assessed.

Tools and technique-data collection

The WHO-UNICEF EVM tool version 1.0.9 was used for the assessment. The tool was downloaded from the link sent by E-mail after creating profile and doing registration on EVM website (https://extranet.who.int/evm/). The basics of the EVM tools were learned through online EVM training course under guidance of nodal officer of NCCVMRC. NCCVMRC is the technical resource center for implementation support related to Cold Chain and Vaccine Logistics Management interventions and for generating the evidence base for further innovations in Cold Chain technologies. The EVM course was pursued on EVM e-learning website and completed on August 6, 2016.

The tool has a comprehensive structured questionnaire for the assessment of ISC. Questions pertaining to CCEs status and their management from the WHO-UNICEF EVM tool were used for the present study. Both primary and secondary data were collected. The primary data were collected by direct observation and interviews of staff responsible for the maintenance of ISC at the designated CCP/HF (also known as VCCH = Vaccine and Cold Chain Handler). A total of 61 VCCH were interviewed in the assessed sites. Secondary data were collected through records available at the CCPs/HFs.

The ethical approval was obtained from Ethics Committee of NIHFW. The data were collected after taking permission from the respective administrative heads of the selected government HFs.

These data were analyzed using the WHO-UNICEF EVM tool and Microsoft excel 2016.

Results

There were a total of 56 electrical CCEs in the assessed sites. These CCEs included 2 large ILR and 1 large Describing Function (DF) in DVS and 24 domestic refrigerators, 22 small ILRs, and 7 small DFs in 29 HFs.

Of 29 assessed sites, 21 (72.4%) CCPs were using the domestic refrigerator for vaccine storage. Domestic refrigerators are not recommended by the WHO for vaccine storage as they do not have any hold over time (duration for which vaccines can be stored without power).

Twenty-three out of 29 (82.8%) of CCPs were not preparing the ice packs in recommended equipment. They were using the domestic refrigerator. These 23 CCPs were using the domestic refrigerator for preparing their ice packs. It was found that 11 Ice Lined Refrigerators received in 11 different CCPs were yet to be installed (all of them had received ILRs during the past 6–8 weeks before data collection for this study started). The status of this electrical equipment is presented in Figure 1.

In assessed sites, 5 of 56 (8.9%) electrical CCEs were found to be nonfunctional (not working), 27 out of 56 (48.2%) CCEs were not complying with WHO standards (make and model of these CCEs was neither listed in WHO Physical Quality Specification Catalogue nor matches the standard specifications). These CCEs included 24 Domestic Refrigerators, 2 small ILRs, and 1 small DF. Domestic refrigerators are not recommended as they do not have any hold over time. The 2 small ILRs and 1 small DF which were noncompliant with WHO standards were found to be CFC equipment which is not recommended by WHO standards. All 24 domestic refrigerators had integrated voltage stabilizer while in 32 other CCEs, 6 of them did not have attached functional voltage stabilizers. Out of these 6 CCEs, 3 were small ILRs and 3 were small DFs. Out of 22 small ILRs, 11 were not installed.

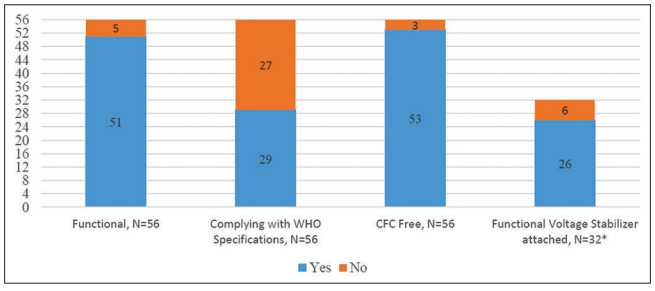

Figure 1: Status of electrical cold chain equipments.

There were 43 functional CCEs in visited sites for vaccine storage. These were 2 large ILRs, 19 small ILRs, 1 small DF, and 21 domestic refrigerators. Forty-one out of these 43 had temperature monitoring device installed them. The details of temperature monitoring devices are presented in Table 1.No continuous temperature recorder/30 days refrigerator logger was found in the visited sites. All of the functional ILRs were fitted with correct storage baskets.

Compliance status of passive containers

There were 121 non-electrical CCEs in the assessed sites for routine immunization program-16 cold boxes (5 large and 11 small) and 105 vaccine carriers. Standard Passive containers had internal dimensions sufficient to accommodate the largest tolerance of the WHO approved standard ice packs and accommodate the number of ice packs as recommended by the manufacturer. The WHO standard ice packs are those which conform to the recommended dimensions, weight, and water content.

Overall, 86% (104/121) of the passive containers were complying with WHO standards in the visited sites. Separately compliance for cold boxes was 62.5% (10/16) and for vaccine carrier was 89.5% (94/105).

The DVS of the district had all standard electrical and nonelectrical CCEs. In 29 assessed CCPs/HFs, the available, functional, and in use standard electrical vaccine storage equipment were found in only 7 (24.1%) HFs and standard ice pack preparation storage equipment were found in only 4 (13.8%) HFs.

As per the WHO recommendations and as per vaccine flow pattern mentioned in the National Cold Chain Assessment India 2014, DVS should have sufficient storage capacity for vaccines storage and icepacks preparation and storage for maximum stock of 2 months and buffer stock of 15 days. The assessed DVS was in practice of storing and indenting immunization supply for maximum stock of 1 month and buffer stock of 15 days. The capacity for vaccine storage and ice packs storage in the assessed DVS was sufficient for only 1 month. The detail for storage capacity in HF is presented in Figure 2.

In 29 assessed CCPs/HFs, for a period of maximum stock of 1 month and buffer stock of 15 days, the storage capacity was insufficient for vaccine storage in 1 (3.4%) HF, icepacks preparation and storage capacity in 7 (24.1%) HFs and passive container storage capacity in 19 (65.5%) HFs. The passive container storage capacity requirement was calculated using

Table 1: Temperature monitoring devices in different vaccine storage equipments

Thermometer	Functional equipment for vaccine storage ($n=43$)			Total thermometers available in the CCEs ($n=43$), n (%)
	ILR ($n=21$)	Domestic refrigerator ($n=21$)	Deep freezer ($n=1$)	
Dial thermometer	0	6	1	7 (16.3)
Stem thermometer	21	11	0	32 (74.3)
Digital thermometer	0	2	0	2 (4.7)
No temperature recording device	0	2	0	2 (4.7)

CCEs: Cold chain equipments, ILR: Ice Lined Refrigerator

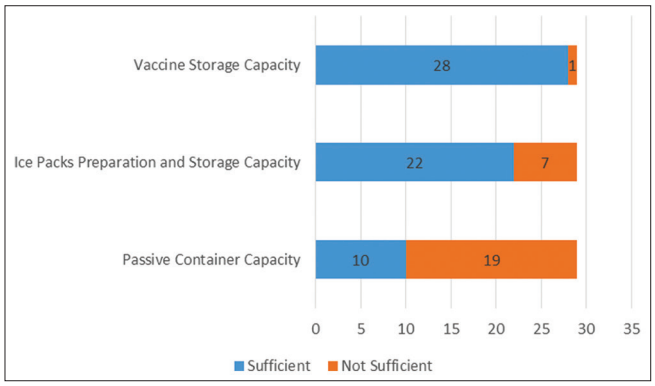

Figure 2: Storage capacities in health facilities ($n = 29$).

the maximum number of outreach sessions planned and possibility of emergency event.

Documented Standard operating Procedures were not found in 28 out of 29 HFs for the management of emergency events such as power failure, mechanical breakdown of equipment, and other emergencies. The emergency contact details for the management of such events were posted in 21 out 29 (72.4%) of the assessed HFs. Documented SOPs in the context of emergency event management were not available at the DVS while the emergency details were posted there. The written Planned Preventive Maintenance SOPs or guidelines were not found at any of the assessed CCPs including DVS. The formal responsibility for the maintenance of CCEs was assigned to the primary VCCH at DVS, but no visual evidence of its maintenance (recent defrost) was found during the assessment. In HFs, the formal responsibility was not assigned to any of VCCH but recent defrost activity was found in 11 out of 29 (37.9%) of HFs. There was no cold chain technician in the district for more than the past 8–9 months. Any repair work of the CCEs was done by hired local engineer.

Discussion

The standard equipment for vaccine storage was available, functional and used in 24.1% visited HFs and for ice packs, preparation and storage in 13.8% visited HFs in this study. In contrast, the study by Rao *et al*.[15] in coastal South India shows that ILRs were available in 98.6% of the centers and DFs were available in 95.8% of the centers and in a study by Gupta and Gupta[16] in Damoh District of Madhya Pradesh, the ILRs and DFs were available in 100% of the centers and in a study by Yakum *et al*.[17] in Cameroon, the functional refrigerators were available in 81.5% of the visited HFs. The findings of the current study are in line with findings of a study by Rogie *et al*.[18] in Ethiopia, where only 19% of the visited HFs were having the functional refrigerator. In this study, temperature-monitoring devices were not available in 2 out of 43 (4.7%) of the vaccine storage devices and 16.3% of the vaccine storage devices had the dial thermometers, which were not calibrated since many years. In a study by Rao *et al*.[15] dial thermometer was present in all the vaccine storage devices and in a study by Gupta and Gupta,[16] the functional thermometer was available in all the CCEs. In this study, voltage stabilizers were available in all ILRs and in 83.3% of the DFs while in a study by Rao *et al*.,[15] voltage stabilizers were available in 97.2% of the centers and in a study by Gupta and Gupta[16] functional voltage stabilizers were found available in 66.7% of the visited centers.

As per the WHO, the recommended stock levels at DVS are maximum of 2 months and safety stock of 15 days. In the selected district, the maximum stock kept at DVS was for 1 month and safety stock for 15 days. Accordingly, the storage capacity was found adequate for vaccine storage in the selected district at DVS but in contrast, the storage capacity was found adequate only in 18% of the assessed DVS in National EVM assessment 2013.[13] In national assessment, the WHO recommended stock levels were followed. The storage capacity had met the recommended standards in EVM assessment of Manipur,[19] Madhya Pradesh,[20] and Tripura[21] at DVS level. Vaccine Storage capacity was found sufficient in 96.6% of assessed HFs in the selected district while the vaccine storage capacity was found adequate in 85% of HFs in National EVM India 2013.[13] Passive containers capacity was found sufficient in 85% of HFs in National EVM India 2013, while it was found sufficient only in 34.4% of HFs in the assessed district. In this study, there was inadequate passive container capacity in 65.5% of assessed HFs. In contrast, the study by Rao *et al*.[15] show that passive containers were adequate in 97.2% of the visited centers.

Being a single researcher and due to time constraints, only one district was assessed. The CCEs status in HFs of Delhi cannot be generalized by assessing only one district. The storage capacity was assessed only for routine immunization and not for Pulse Polio Immunization.

Conclusion

The district HFs are facing a shortage of standard equipment for vaccine storage, ice packs preparation, storage, and

passive containers. Nonrecommended domestic refrigerators are still being used. Findings of the study indicate overall inadequacies of most of the essential components of EVM in the district which needs urgent measures from the district program managers.

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Conflicts of interest

There are no conflicts of interest.

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