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Research Article

COLD CHAIN MANAGEMENT FOR IMMUNIZATION IN AURANGABAD DISTRICT

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A R T I C L E I N F O

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A B S T R A C T

Background: Immunization is one of the most important among activity in the Public Health Services to prevent the vaccine preventable diseases. The vaccines are highly heat or cold sensitive and vaccine potency once lost cannot be restored. A well-managed cold chain will increase the efficiency of immunization and reduce vaccine wastage. An assessment of cold chain system for vaccine storage was done in selected PHCs of Aurangabad districts.

Aims & Objectives: To evaluate the cold chain practices, with particular reference to assessing the availability of cold chain equipment, vaccine storage practices, monitoring of cold chain in primary health centres (PHCs) of Aurangabad district.

Material & Methods: A cross-sectional study was conducted at selected the cold chain points in 15 PHCs of Aurangabad district during Aug to Oct 2018. A predesigned, pretested checklist was used by the trained investigators during their visits. The information was evaluated on the basis of important components related to the cold chain points.

Results: All the PHCs had a dedicated vaccine storage room with sufficient number of cold chain equipment. Vaccine storage practice and availability of complete RI micro-plan were found satisfactory at all 15 (100%) PHCs. Maintenance of cold chain equipments were satisfactory at 11 (73.3%) PHCs. But, temperature monitoring. (9) (60%) by Medical Officer and waste disposal related to routine immunization 10 (66.6%) at PHCs were disappointing.

Conclusion: The primary health centers had average performance related to the cold chain system, which is a matter of concern warranting for the cold chain monitoring. We recommend supportive supervision as the key measures in improvement of cold chain system.

INTRODUCTION

Immunization is a crucial component of the Public Health Services. Immunization prevents illness, disability and death from vaccine-preventable diseases including diphtheria, hepatitis B, measles, mumps, pertussis, pneumonia, polio, rotavirus diarrhoea, rubella and tetanus etc. Immunization currently prevents an estimated 2 to 3 million deaths every year. (1) Immunization is acknowledged among the most cost-effective and highest health-impact interventions.(2)

India launched its first vaccine – BCG in 1962 as a part of National Tuberculosis Program. (3) The Expanded Programme on Immunization (EPI), a national programme for immunizing all children during the first year of life with Diphtheria, Pertussis and Tetanus (DPT), Oral Polio Vaccine (OPV), Bacilli Calmette Guérin (BCG) and typhoid–paratyphoid fever vaccines was launched in 1978. In 1985, the name of EPI was changed to the Universal Immunization Programme (UIP) to cover all districts in a phased manner by 1990 with a lofty goal to cover all the eligible under five years children against six vaccine preventable diseases and all pregnant women with TT vaccine. (4)

The vaccines used in the UIP are highly temperature sensitive regarding their potency. The quality of vaccination services is important for achievement of the ultimate goal of disease reduction. There are many gaps in the area like storage of vaccines, temperature monitoring in routine activities. Suboptimal seroconversion rates and outbreaks of vaccine preventable diseases elsewhere were attributed to loss of vaccine potency either during transportation or storage. (5) Vaccine potency once lost cannot be restored. Hence, the backbone of the efficient immunization system is the maintenance of cold chain. Cold chain refers to the network of equipment, personnel and processes that ensures that vaccines are transported and stored at appropriate temperatures up to the point of administration, ensuring that they retain their potency. A well-managed cold chain will increase the proportion of effective vaccines that are administered and reduce vaccine wastage.(2) Hence, the cold chain system requires attention for effective vaccination programme. There is paucity of

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information on this issue in the Aurangabad district of Maharashtra.

Aims & Objectives

To evaluate the cold chain practices, with particular reference to assessing the availability of cold chain equipment, vaccine storage practices, monitoring of cold chain in primary health centers (PHCs) of Aurangabad district of Maharashtra.

MATERIAL & METHODS

Study settings

The evaluation of the cold chain system for routine immunization programme at was conducted at selected 15 PHCs of Aurangabad district of Maharashtra, India. The important equipment in cold chain system are mainly the electrical cold chain equipment like ice-line refrigerators (ILRs), deep freezers (DFs) and voltage stabilizers.

This district has an area of 10100 sq. kms and a population of 3.7 millions in 2018.(6) The district has 50 PHCs. PHC plays important part in immunization of rural area.

Study design*:* Cross-sectional observational study conducted during Aug to October 2018.

Study unit

The cold chain systems of 15 primary health centres of the district were included. PHC were selected by random selection method.

Data Collection

The ethical approval from the ethical committee of SHSRC was taken prior to start the study. Prior permission was obtained from the District Immunization Officer of Aurangabad. The health centres were visited by the investigators and the investigators were imparted training for the assessment before initiation of these activities. The physical verification of the available cold chain equipment was done and their functional status was also examined during each visit by the investigators.

A predesigned and pretested checklist was used to collect the data. The information was collected from cold chain handler and medical officer in charge for routine immunization of the respective cold chain system at PHC. The information was evaluated on the basis of important aspects related to the cold chain system. These components were related with status of cold chain system, routine micro-plan, status of all cold chain equipment and their maintenance, temperature monitoring practices, vaccine storage practices, vaccine and logistics management, recording and reporting system and waste disposal activities. Storage practices of vaccines and diluents were also assessed on the recommendation about placement of heat and freeze sensitive vaccines, returned partially used and unused vaccine vial under open vial policy.

The cold chain handlers available during the visit were interviewed to assess their training and knowledge regarding cold chain. The questionnaire included questions on information of the respondent related to knowledge regarding management of the cold chain including the recommended storage temperature range, use of vaccine vial monitor (VVM), use of diluents, storage in deep freezer, the shake test.

Statistical Methods

All the results obtained will be analyzed using suitable statistical software.

RESULTS

Out of total 15 PHCs in study, the trained cold chain handlers were present at 14 (93.34%) PHCs. At 12 (80%) PHCs, LHV/HA were working as cold chain handlers whereas at rest of PHCs the work of cold chain handling was being done by other category of staffs such as pharmacist, dresser etc. Session wise routine micro-plan was available at 13(86.67%) out of PHCs.

Status of Functional Cold chain equipment (Electrical) at the PHCs

As the availability of cold chain equipment are concerned the non- electrical equipment were sufficient in all primary health centres. At least one of each of the electrical equipment - ILR and DF were present in all PHCs. The domestic type of refrigerator and mini refrigerators were not being used for storage of vaccines and diluents at any of primary health centre.

All PHCs have separate cold chain room in which all the vaccine storage equipment were kept. The ILRs and DFs were placed away from sunlight and moisture at all the PHCs. The ILRs and DFs were properly placed 10 cm away from the wall in all PHCs and in only 11 (73.33%) PHCs, the ice lined refrigerators and deep freezers were kept on wooden block. The separate voltage stabilizers for cold chain equipment (ILR & DF) were present in only 8 (53.34%) PHCs (Table 1). In 4 (26.67%) PHCs, the icepacks were correctly placed in deep freezers. At 13 (86.67%) PHCs, all functional cold boxes were clean and dry from inside. In 8 (53.34%) PHCs, cold chain technician visited facility in previous 3 months for preventive maintenance.

Table 1 Status of Functional Cold Chain Equipment (Electrical) In The PHC

Functional Equipment	ILR	DF
	No (%)	No (%)
Placed away from sunlight, moisture	15 (100.00)	15 (100.00)
Placed 10 cm away	15 (100.00)	15 (100.00)
Wooden block	11 (73.34)	11 (73.34)
Separate Voltage Stabilizer	8 (53.34)	8 (53.34)

Storage Temperature monitoring Practices (Functional Electrical CCE)

Table 2 Storage Temperature Monitoring Practices (Functional Electrical CCE)

Functional Equipment	ILR	DF
	No. (%)	No. (%)
Functional thermometer placed inside every functional equipment	15 (100.00)	13 (86.67)
Cabinet temperature within recommended range	15 (100.00)	12 (80.00)
Separate standard printed temperature log books available	15 (100.00)	15 (100.00)
Temperature records noted down twice daily	12 (80.00)	12 (80.00)
Log books reviewed by facility in charge at least once every week	6 (40.00)	6 (40.00)
Frost free	11 (73.34)	10 (66.67)
Record of power failure maintained in temperature log books	2 (13.34)	2 (13.34)
Records of defrosting maintained in temperature log books	1 (06.67)	1 (06.67)

As shown in Table 2, functional thermometers were placed in ILR in all 15 PHCs where as functional thermometer in DF found only in 13(86.67%) PHCs. However, in 15 (100%) PHCs the cabinet temperature was within recommended range for ILR and only 12 (80%) for DFs. Separate standard temperature log book was available for ILR and DFs at all PHCs which were supplied by district administration. In 12 (80.00%) PHCs, temperature was noted twice daily for ILR and in case of DFs twice daily recording was being done at 12 (80.00%) PHCs. The temperature log book for ILRs and DFs were reviewed by Medical officer only at 9 (60%) PHCs. At 4 (26.67%) PHCs the ILRs were frost free but in only 5 (33.34%) PHCs, the DFs were frost free. Records of power failure and defrosting were maintained in only two PHC (13.34%). However, in all of the PHCs, there were regular power supply and back-up generator services available.

Status of Vaccine Storage Practices

Table 3 Status of Vaccine Storage Practices

	Yes (%)
All vaccine vials correctly arranged in order from bottom towards upwards (as per norms)?	13 (86.67)
RI vaccines stored inside DF	0 (0.00)
Vaccines stored are within expiry dates	15 (100.00)
VVM status of stored vaccines is in usable stage (Stage I & II)	14 (93.33)
Reconstituted BCG, Measles or JE vaccines found stored	0
Items other than vaccines used for routine immunization stored inside ILR	1 (06.67)
All diluents placed inside ILR (at least for next session day)	10 (66.67)
Opened vial of any vaccine stored inside any ILR	15 (100.00)
If yes, are they stored separately inside ILR?	15 (100.00)
Are these returned unused vials distributed on priority on next session day?	13 (86.67)
Whether Stock register has been updated till last session day?	7 (53.34)

In 13 (86.67%) PHCs, the vaccines were correctly arranged from bottom to upwards as per norms (Table-3).In None PHCs, RI vaccines were stored inside DFs. Expired vaccines were not stored in ILR/DF at any PHC. The VVM status of stored vaccines was within the usable stages at most of the PHCs i.e. 14 (93.37%) whereas at 1 PHCs the oral polio vaccines of stage 3 were stored in ILR. Reconstituted vaccines were not stored in any of cold chain equipment at any place. At 1 (6.67%) PHCs, items other than vaccines like anti rabies vaccine, water bottles were stored inside ILR/DF. At all 15 (100%) PHCs, opened vials of vaccines were stored in ILRs and they were placed separately in ILR. Returned unused and used vials under open vial policy were distributed on priority basis on next session day in 13 (86.67%) PHCs.While in 2 (13.34%) PHCs open vial are seen more in numbers draws the conclusion that they were not being used on a priority basis. The updated stock register was available at only 7 (46.67%) PHCs.

DISCUSSION

Childhood immunization is among the most cost-effective health interventions and India has one of the largest immunization programmes in the World. All the vaccinated children are considered immunized only when their sero-conversion level is within the accepted normal value. Sero-conversion of the individuals is affected by various internal and external factors. The external factors are related to the vaccines such as maintenance of cold chain equipment, vaccine storage and temperature monitoring. These are very critical for determining the potency of vaccines. Hence, the cold chain system remains a highly vulnerable element of any immunization programme.(2)

This study focused on investigating the availability and maintenance of electrical cold chain equipment, temperature monitoring and vaccine storage practices in Aurangabad District of Maharashtra. In present study, 93.34% of PHCs had availability of trained cold chain handlers as compared with study of Sanjay Pandey et al at Bhojpur district oh Bihar in 2015. Presence of ILR and DF are one of the basic cold chain equipment which any health facility needs to have for efficient cold chain maintenance. (8) In this study, all the PHCs had sufficient number of functional ILR and DF and this showed better status than the observations made in different areas of India. (5, 9, 10, 11) Exposure to sunlight will lead to increase in core temperature of the cold chain equipment, which would break the cold chain by causing an increase in the core temperature of ILR and deep freezer. This causes exposure of vaccines to higher temperature than required. In the present study, there was a separate room dedicated for cold chain equipment in all the PHCs of the district. The deep freezer and ice-line refrigerators were placed away from the direct sunlight at all places and placed at least 10 cm away from the wall at all places as compared with study of Sanjay Pandey et al at Bhojpur district oh Bihar shows 85.7%. This was similar to the finding reported in several other studies. (8, 10, 11).

As per the standard norm, the present study showed that in 8 PHCs (53.34%), separate voltage stabilizer was attached each to deep freezer and ILR. Shortage of voltage stabilizers was also reported in several other studies (11,12,13,14).

The potency of vaccines depends on maintaining the cold chain within a prescribed temperature range of 2-8°C during storage and transport. A break in the cold chain is indicated if temperature rises above +8°C or falls below +2°C in the ILR and above −15°C in the deep freezer. Thus, the ILR and deep freezers, each should have a separate functional thermometer and updated temperature record book. In the present study, functional thermometer in ILRs and DFs was available only in all PHCs for ILR while in 13 (86.67%) for DF most of these PHCs having in built digital thermometer outside the ILR and DF, This finding shows more satisfactory results as compared with previous study of Sanjay Pandey et al in Bihar. But, temperature was being recorded twice a day for both deep freezer and ILR in 12 (80%) of the health centres in separate temperature record books which was indicating the real fact regarding the temperature monitoring of electrical cold chain equipment for vaccine storage. This was equivalent as compared to other studies conducted in India. (9,11,12,14)
The temperature in the ILR/freezer can also rise due to presence a thick layer of ice around the freezer or along the walls and bottom of ILRs. It is therefore necessary to defrost them periodically. This should be done if the ice in the freezer is >5 mm thick. The present study showed that defrosting of ILRs and deep freezers was very irregular and recording of the defrosting record in register was done only in one of the health centres. However, on observation, the ILRs were frost free in 11 (73.34%) PHCs, but for DFs, it was frost free only in 10 (66.67%) centres. The similar practice for defrosting and maintenance of its record for ILRs and DFs were reported in other studies. (10,11) while study of Sanjay Pandey et al shows much less percentage as 64% and 35% for ILR and DF respectively.

Vaccines lose their potency due to exposure to excessive heat or excessive cold and were not effective if administered to the beneficiary. Freeze sensitive vaccines like T-series vaccines (DTP, TT, Pentavalent) and Hepatitis-B may be damaged by exposure to freezing temperatures and hence it is crucial to store them between +2°C and +8°C temperature. (15, 16, 17) Diluents vials also must not be frozen as it may cause the glass to crack and cause contamination of the content. In the present study, vaccines were arranged as per guideline in approximately in 86% of the centres. OPV was stored in ILR only at all places. These finding of the study were in similar to the results of the studies reported in various places. (9,11,12) It is also important that VVM status does not indicate if a vaccine has been frozen. Thus, the cold chain handlers need to understand the importance of this arrangement, as impotent vaccines give a false sense of security against vaccine preventable diseases, which a child would contract later on despite the vaccination.

The concept of Vaccine Vial Monitor (VVM) was conceived in 1997 and formally introduced for all UNICEF procured OPV vials in 1996 and slowly expanded to other heat sensitive vaccines. VVM technology was introduced for heat labile vaccines with two-fold intent: to reduce vaccine wastage and to identify heat damaged stock thus preventing administration of less efficacious vaccine to the beneficiaries. In our study, the vaccine stored in the ILR at 14 (93.34%) PHCs were within usable VVM stage. Similar results were reported from various studies where vaccines were in usable condition. (9,10,18,19)

Lyophilized vaccines such as measles vaccines need to be kept cold and to be used within 4 hours after they have been reconstituted. Otherwise, such vaccines lose stability and are at increased risk of bacterial contamination. No reconstituted vaccines were stored in the ILR in any places as reported in the study.

As per the guidelines, diluents are to be stored in ILR. If there is space constraint, it can be stored outside. (20) But, they have to be cooled at least 24 hours before use to ensure that both vaccines and diluents are at +2° to +8°C when being reconstituted or else might lead to thermal shock. In our study, diluents were stored in ILR in 66.67% of centres at least 24 hours before use as informed by the cold chain handlers. As per the Multi Dose Vial Policy (MDVP)/Open vial policy guidelines, the multi-dose vials of vaccines except reconstituted vaccines of BCG, Measles, JE opened in a fixed or outreach session can be used at more than one immunization session up to four weeks provided that a) they are within expiry date, b) the vaccines are stored under appropriate cold chain conditions both during transportation and storage in cold chain storage point, c) the vaccine vial septum has not been submerged in water or contaminated in any way, d) the vaccine vial monitor (VVM) should be within usable stage and e) aseptic technique has been used to withdraw all doses. (7) In the present study, open vial vaccines were collected, stored and reused on priority basis in 13 (86.67%) the centres.

CONCLUSION

As per our study, all the centres have dedicated cold chain room with the availability of functional ILR and DF. As regarding the various activities related to cold chain points in the Aurangabad district of central Maharashtra like vaccine storage practice, availability of complete RI micro-plan, availability of trained cold chain handlers and maintenance of cold chain equipment were found to be satisfactory. The cold chain monitoring status in the district is inadequate to ensure proper vaccine storage as the activities like temperature monitoring by Medical Officers and record maintenance were not proper. There is a grave concern on the status of the cold chain monitoring since it can cripple the immunization program. Waste disposal related to routine immunization needs much attention.

Recommendation

It is recommended that continuous training and supportive supervision of the cold chain system at the primary health centres should be taken up in regular manner which is the key measures to address the findings of this study.

References

1. Immunization coverage: Fact Sheet (WHO). Available at www.who.int /mediacentre /factsheets/fs378/en/ (Accessed on May 13, 2018).
2. Pandey S, Singh CM, Ranjan A, Kumar Y, Kumar P, Agarwal N Assessment of Cold Chain System for Routine Immunization of Primary Health centres of the Bhojpur district of Bihar Indian J Comm Health. 2018; 30, 2: 120-126.
3. Vashishtha VM, Kumar P. 50 years of Immunization in India: Progress and Future. Indian Pediatr 2013;50: 111-118
4. Government of India. National Effective Vaccine Management Assessment: India; 2013 [Available from http://unicef.in/Uploads/Publications/Resources/pub_doc86.pdf] Accessed on March 23, 2018
5. Rao S, Naftar S, Baliga S, Unnikrishnana B. Evaluation, Awareness, Practice and Management of Cold Chain at the Primary Health Care Centres in Coastal South India. J. Nepal Paediatr. Soc. 2012; Vol 32(1):19-22.
6. https://www.censusindia2011.com/maharashtra/aurangabad-population.html Accessed on Oct 31, 2018.
7. National Effective Vaccine Management Assessment India, 2013: http://unicef.in/Uploads/Publications/Resources/pub_doc106.pdf Accessed on March 03, 2018.
8. Government of India. Immunization hand book for Medical Officers. Ministry of Health & Family Welfare, New Delhi; 2008. [Available from http://nihfw.org/pdf/NCHRC Publications /ImmuniHandbook.pdf] (Accessed on March 07, 2017).
9. Krishnappa L, Anniappan AB, Voderhobli NH, Krishna SK, Yathiraj S, Sreekantaiah P. Evaluation Of Cold Chain Practices In Urban Health Centers Of A Metro City In India. *Natl J Community Med* 2014; 5(3): 288-292.
10. Nandan D, Jafari H, Datta U, Bahl S, Renuparuthi, Bhattacharya M *et al*. Performance Assessment of Health Workers Training in Routine Immunization in India (WHO and NIHFW collaborative study).India: December 2009.
11. Sachdeva S, Datta U. Status of Vaccine Cold chain maintenance in Delhi, India. Ind J Med Micro 2010; 28(2): 184-185.

12. Naik A K, Rupani M, Bansal RK. Evaluation of vaccine cold chain in Urban Health Centres (UHCs) of Municipal Corporation of Surat city, Western India. Int J Prev Med 2013; 4:1395-401.
13. Bachani D, Bansal RD. Logistics management in Universal Immunization Programme. Indian J Public Health. 1990;34:179–84.
14. Mallik S, Mandal PK, Chatterjee C, Ghosh P, Manna N, Chakrabarty D, *et al*. Assessing cold chain status in a metro city of India: An intervention study. Afr Health Sci. 2011;11:128–33.
15. Guidelines on how to maintain vaccine cold chain. Available at:https://www.moh-ela.gov.sg/ela/content/ Vaccine_Cold_Chain.pdf2005. (Accessed on March 11, 2018).
16. World Health Organization, Department of Immunization, Vaccines and Biologicals, Geneva. Training for mid-level managers (MLM) - Module 1. Cold chain, vaccines and safe-injection equipment management. Geneva, Switzerland: WHO; 2008. p17. Available from http://whqlibdoc.who.int/hq/ 2008/WHO_IVB_08.01_eng.pdf (Accessed on May 11, 2018).
17. Murhekar MV, Dutta S, Kapoor AN, Bitragunta S, Dodum R, Ghosh P, et. Al. Frequent exposure to suboptimal temperatures in vaccine cold-chain system in India: results of temperature monitoring in 10 states. Bull. World Health Organ 2013;91: 906–913.
18. Patel T, Raval D, Pandit N. Process evaluation of routine immunization in rural areas of Anand District of Gujarat. Health line 2011; 2(1):17-20.
19. Samant Y, Lanjewar H, Block L, Parker D, Stein B, Tomar G. Relationship between vaccine vial monitors and cold chain infrastructure in a rural district of India. Rural and Remote Health. 2007; 7:617. Available from: http://www.rrh.org.au. (Accessed on May 12, 2018)
20. Govt. of India. Handbook for vaccine and cold chain handlers. Ministry of Health & Family Welfare, New Delhi; 2010.

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