

Original Article

EVALUATION OF COLD CHAIN PRACTICES IN URBAN HEALTH CENTERS OF A METRO CITY IN INDIA

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INTRODUCTION

India has one of the largest immunization programmes in the world¹ and childhood immunization is one of the most cost effective public health interventions.² In order to realize the full benefits of immunization, coverage of vaccination has to be increased and more importantly potent vaccines should reach the beneficiaries for which cold chain maintenance is crucial.^{1,3}

National family health survey (NFHS-3) reports revealed that in Karnataka, the percentage of children in the age group of 12-23 months who were fully immunized with one dose of BCG, measles and 3 doses of Oral polio vaccine (OPV) and Diphtheria, Pertussis and Tetanus(DPT) was 55.0%.⁴ In this regard, Government of Karnataka undertook state wide training of medical officers and health workers on Routine immunization (RI) in 2008. Concurrent efforts made to

ABSTRACT

Background: National Family Health Survey report (NFHS)-3 reports revealed that immunization coverage in India among children between 12-23 months was low at 43.5%. In lieu of strengthening Routine Immunization (RI), Government of Karnataka undertook state-wide training of Medical officers and Health workers on RI with concurrent efforts of strengthening cold chain system in health centers. With this background, this study was undertaken to assess the cold chain practices in urban health centers of Bangalore city.

Methodology: This Cross-sectional study was conducted during October-December 2008 in three-zones of Bruhat Bangalore Mahanagara Palike (BBMP) covering 35 units. Physical verification of the available cold chain equipments was done using predesigned pretested checklist and face to face interview of cold chain handlers was employed.

Results: Of 35 centers, 33(94%) and 32(91%) of them had atleast one functional Ice-lined refrigerator(ILR) and one deep freezer(DF) respectively. Good storage code practice was practiced in 12 out of 33 ILRs. Functional thermometer was available in 31(91%) ILRs of which 23(74%) had temperature in the recommend range. With respect to knowledge of cold chain handlers on RI, 86% were trained on RI and their overall knowledge regarding cold chain practices was satisfactory except for knowledge on temperature in DF and on conditioning of ice-packs.

Conclusion: Availability of cold chain equipments has improved and Cold storage practice was good/fair in most of the centers. Knowledge of cold chain handlers was low with respect to select cold chain practices.

Key words: Cold chain, Ice lined refrigerator, Deep freezers, Urbanhealth centers, India

strengthen cold chain system at government level by providing right cold chain equipments. With this background, this study was carried out with the objective of evaluating the cold chain practices, with particular reference to assessing the availability of cold chain equipment, vaccine storage practices, monitoring of cold chain and knowledge regarding vaccine storage amongst the cold chain handlers' in urban health centers of Bruhat Bengaluru Mahanagara Palike (BBMP) area.

METHODOLOGY

Study design: This was a cross-sectional observational study conducted during October to December 2008.

Study unit: Urban health centers of BBMP area. For administrative purpose, BBMP area is divided into

three zones namely east, west and south zones and each zone has two referral hospitals; with each referral hospital covering five to seven urban health centers. Total such 68 urban health centers are present in these zones each catering to a population of 50,000 to 1 lakh on an average.

Sample size: Preliminary pilot study revealed that compliance to cold chain practice was 90%. Based on this, sample size for the study worked out to be 35 urban health centers at 95% confidence level.

Sampling method: List of all urban health centers/ maternity homes in BBMP area constituted the sampling frame. Using simple random sampling technique 35 units were sampled with equal representation of all the three zones covering six referral hospitals.

Statistical analysis: Statistical analysis was done using SPSS version-16. Descriptive statistics is used.

Study tool: Pre-designed pre-tested observational checklist and questionnaire.

Prior permission was obtained from the immunization officer of the BBMP area to include the health centers for the study. For confidentiality purpose, none of the health centers included in this study is identified by name. Sampled health centers were visited by the investigator and physical verification of the available cold chain equipments was done using a predesigned pretested checklist. In addition, the cold chain handlers available during the visit were interviewed to assess their training status and their knowledge regarding cold chain.

Components evaluated in the study were cold chain equipments status, cold storage code, cold storage monitoring activities, training status and knowledge of the cold chain handlers regarding cold chain. Equipments included both electrical and non-electrical equipments. The electrical cold chain equipments i.e Ice lined Refrigerator (ILR), deep freezers (DF) and Domestic refrigerator were specifically evaluated for (i.) availability and maintenance (ii) functioning of cold chain equipments (iii) adequate temperature maintenance. Non-electrical cold chain equipments such as vaccine carriers, cold boxes were examined for availability, adequate maintenance (not cracked and properly fitted lids) and its condition with respect to hinges and gaskets. Ice packs evaluated for their adequacy on basis of Pulse Polio Immunization micro-plan and for its maintenance in terms of good condition with presence of both inner and outer caps.

Cold storage code was assessed based on training guideline recommendations where OPV, BCG, Measles to be stored in lower basket; T-series vaccines and Hepatitis-B vaccine in upper right basket; returned partially used/ unused vials and diluents in the left upper basket.⁵ Cold storage monitoring was assessed by actual documentation of the temperature in ILR and DFs at the time of visit and verification of the temperature-monitoring chart. Availability of alternate plan in event of electrical failure was docu-

mented. All vaccine vials were inspected for expiry dates, frozen state and vaccine vial monitor (VVM) status recorded as per UNICEF guidelines.¹ Training status and knowledge of the cold chain handlers: was assessed using a pre-designed checklist.

RESULTS

According to BBMP source, out of 68 centers 57(84%) and 43(63%) centers had ILR and DFs respectively. Session wise micro-plan was not available in any of the centers.

Status of cold chain equipments: Of the total 35 units sampled, 33 (94%) and 32(91%) centers had atleast one ILR and one deep freezer respectively which were functional and in good condition (Table-1). While in one centre, vaccines were stored in domestic refrigerator, in another centre it was stored in deep freezer converted ILR. In all the centers, ILR and DFs were correctly located (atleast 10 cm away from the wall and away from direct sunlight and placed on wooden block) (Table 2). Of the 34 ILRs, 28(82%) had do's and don'ts and 13(38%) ILR had their electric plugs secured in place. Make of all 34 ILRs was Haier Company while make of DFs were of Blue Star, West Frost, UNICEF supplied, Cold Cell.

Twenty-seven centers had domestic refrigerator, of which only one center used it exclusively for vaccine storage because of non-availability of ILR. Despite the availability of ILR, Tetanus toxoid (TT) vaccines were still stored in domestic refrigerators in 10 centers.

Deep freezers were used for making and storing of ice packs in all the centers. Except for one centre, in none of the units vaccines were stored in deep freezer. Of all the centers, only in ten DFs the ice packs were arranged in criss-cross fashion as per guidelines.⁵

Totally 44 cold boxes were examined and in all of them gasket and hinges were found in good condition. Of 35 centers, 33 (94%) had at least one cold box which were used only in event of power failure and sometimes to transport vaccines during pulse polio immunization programme. Adequate number of vaccine carriers and ice packs were available as per micro plan for pulse polio immunization and were in good condition. Those not in good working condition were condemned for use.

Status of vaccine cold storage practices: Vaccine storage practices in the ILR were graded based on the observation, with respect to three different storage criteria namely, (1) storage of BCG and measles vaccine in lower basket, (2) T-series and Hepatitis B vaccine in upper right basket and (3) diluents, returned partially used and unused vials in upper left basket. If all the three were correctly stored, it was considered as good practice, if two were correctly stored, it was graded as fair practice and if only one code was practiced, it was graded poor practice. Accordingly, at the time of visit only 35% of the centers followed good

practice with respect to vaccine storage in ILR (Table-3).

As per guidelines, vaccines are recommended to be stored in baskets placed within the ILR. However, on inspection baskets were used only in 31 ILRs. Checking on frozen status of Freeze sensitive T-series and Hepatitis-B vaccines, looking at the temperature charts of ILRs, we did not suspect any vaccine to be frozen and hence it felt that Shake test was not necessary.

Diluents of BCG/measles supplied along with vaccines were adequate but as per the guidelines, only in 25 centers they were stored in ILR. Except for one centre where HIV testing kit and other injections were stored, in none of the centers either food or other medicines were stored in the ILR. None of the vaccines was found beyond the expiry date. In one of the centre where domestic refrigerator was used for vaccine storage, vaccines were stored as per the recommendations of the UNICEF guidelines.¹

Cold chain monitoring: Functional thermometer was available in 31 (91%) centers and among these only in 15 (48%) centers, thermometer were placed in correct position within the ILR. Of these, 21 were stem thermometers and 10 were dial thermometers. At the time of visit, temperature in cabinet of eight ILRs was not in the recommend range. Though 33 ILRs had external temperature display, only 7(21%) of them were functioning.

Temperature monitoring chart were available in all the centers in which temperature was recorded twice daily. Documentation of power failure in the chart was done in 13(38%) centers and no documentation was available regarding change in temperature in other centers. Of 32, only 15 DF had functional thermometer, out of which only eight DFs had temperature within the recommended range at the time of visit.

VVM of OPV and Hepatitis-B vaccine was found in usable condition (stage 1 and stage 2) in all the centers, except for in one center where the VVM of Hepatitis-B was found in stage 3.

Knowledge status of cold chain handler: Twenty-eight designated cold chain handlers who were available during the visit were interviewed, of which 24 had undergone training on routine immunization in last two years while four of them had not undergone any specific training on routine immunization. Overall, the cold chain handlers had satisfactory knowledge about the cold chain system except for few aspects such as recommended temperature in deep freezer where only 14% gave the correct answer. Only 54% of the handlers knew what conditioning of ice packs meant. While in 16 centers ANMs and in 12 centers other staffs such as staff nurses, lab technicians and pharmacist were designated as cold chain handlers, in seven of the centers there was no specific person designated for monitoring the cold chain.

Table 1: Availability and functional status of cold chain equipments in study centers

Cold chain equipments	Total Unit	Functional Unit
ILR	35*	34
Deep freezer	33*	32
Cold box	44	44
Domestic refrigerator	31	27#

*Note: Few centers had more than one ILR and deep freezer; # only one centre used exclusively for vaccine storage

Table 2: Status of electrical Cold chain equipments in the study centers

Character	ILR (%)	DF@ (%)
Total unit	34	32
Equipments correctly situated#	34(100)	32(100)
Had do's and dont's sticker on the door	28(82)	11(34.4)
Electric Plugs were secured in place	13(38)	5 (15.6)
Availability of functional thermometer	31(91)	15(46.9)
Thermometer placed in correct position	15(48)*	15(100)**
Temp. within recommended range	23(74.2)*	8 (53.3)**

*n=31,**n=15; #at least 10 cm away from the wall and away from direct sunlight, on wooden block; @Deep Freezer

Table 3: Vaccine storage practice in ILR (n=34)

Grading of storage practice	Frequency	Percentage
Good practice	12	35
Fair practice	18	53
Poor practice	4	12

Table 4: Knowledge of cold chain handlers on key areas of cold chain aspects (n=28)

Correct knowledge of	Frequency (%)
Adjusting thermostat control in ILR	21(75)
Temperature in ILR	28(100)
Temperature in Deep freezer	4(14)
Heat sensitive vaccines	28(100)
Freeze sensitive vaccines	26(92)
Conditioning of ice packs	15(54)
Vaccine storage in cold box in event of power failure/ transportation	22(78)

DISCUSSION

Immunization is one of the most cost-effective strategy in reducing childhood morbidity and mortality. Not all vaccinated children are immunized until unless there is sero-conversion. While there are various internal factors that operate in sero-conversion of individuals, which are not under control, there are many external factors such as maintenance of cold chain, which determine vaccine potency. So effective management of cold chain system at all levels is one of the crucial factors for maintaining vaccine potency, which narrows the gap between vaccinated and immunized.

Though many studies on cold chain evaluation have been done in rural areas, very few are done in urban areas. Our study thus focused on evaluating the cold chain practices at the urban health centers of BBMP area.

Presence of ILR is one of the basic cold chain equipment which any health center needs to have for effi-

cient cold chain maintenance. Though domestic refrigerator maintain temperature at +2 to +8°C, they are not recommended for use in universal immunization programme as their holding time is only four hours.^{5]}

In our study, except for one centre where domestic refrigerator was used for storing vaccines, all other centers (97%) used ILR exclusively for vaccine storage and were in good working condition. Our study findings were similar to that observed by Rao et al (98.6%); Goel et al (92.5%) and Doeki et al (78%) studies, which had functional ILR.^{6,7,8} Similarly Samanth et al reported that 73% of the cold chain equipment were present and maintained the required temperature.⁹ Although there may be methodological differences amongst the various studies, significant discrepancy between urban and rural functional cold chain availability is evident.

Cold chain sickness rate at any point in health centers should be to the minimum acceptable level of less than 2%.⁵ In our study, one of the ILR was under repair and hence the cold chain sickness rate for ILR was 2.9% but this high percentage could be due to small samples of ILRs. Goel et al in a study conducted in Chandigarh reported that sickness rate of 9.7% in 2002 had reduced to 6% in 2006.^{7,10}

Only 31 ILR had functional thermometer of which 21 were stem thermometer and 10 were dial thermometer. Alcohol thermometers are more sensitive and accurate as they can record temperatures from - 50°C to + 50°C and can be used for both ILRs and DFs.⁵ In three of the centers where functional thermometers were not available, there was no temperature monitoring chart. In our study, 91% maintained temperature-monitoring chart adequately. 94.2% (Rao et al), 55% (Mallik et al) and 65% (Samanth et al) of the centers have adequately maintained the temperature-monitoring chart.^{6, 11, 9}

While Mallik S et al reported that no organization maintained a chart in case of cold chain failure; Sharma et al reported that 98% of centers recorded power failure.^{11,12} But in our study, 38% centers had documented power failure and alternate measures undertaken. These varied results could be due to effect of training, attitude and practice by cold chain handlers.

Vaccines when not stored or transported at an appropriate temperature can lose their potency and not effective if administered to the beneficiary. Maintaining vaccines at the right temperature though not an easy task, but the consequences of not doing so can be disastrous and hence the crucial need to maintain recommended optimal temperature of +2 to +8°C.^{1,3,5,13} In our study, in 8 (23.5%) ILRs temperature was not in the recommend range. These results concurred with findings of Samanth et al who found that 75% of ILR in primary health centers in rural area and Mallik et al in 80% of centers in metro city maintained temperature in optimal range.^{9,11} In a study done by Harsha Kumar et.al correct temperature was not maintained in 31.25% of the studied health centres.¹⁴

Freeze sensitive vaccines like T-series vaccines (DTP, TT) 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. Diluents vials also must not be frozen as it may cause the glass to crack and cause contamination of the contents.^{3,13} On examination, in our study none of the vaccines or the diluents was found in frozen state. It is also important to note that VVM status does not indicate if a vaccine has been frozen.¹³

As per guidelines, ice packs need to be stacked in criss-cross manner in deep freezer.⁵ This allow even distribution of temperature and proper preparation of ice-packs. In our study, criss-cross arrangement of ice packs was seen only in 23%. Similar observations made in one-third of the health centers of Surat city.¹⁵

Though training was provided on storage code in ILR, good storage practice was seen in only 57% of ILR. Study by Rao.S et al found that improper storage vaccine in 10% of study centers.⁶ Sharma et al in 90% and Tushar et al in 93.2% reported that vaccines were properly arranged in the ILR.^{12,16} This differences could be due to different criteria adopted in labeling good practices. Deep freezers are to be used to prepare ice-packs and not to store vaccines at peripheral centers.⁵ But in our study, it was found in one center that the vaccines were stored in DF converted ILR due to non-availability of ILR.

As per the guidelines, diluents are to be stored in ILR. If there is space constraint, it can be stored outside.^{1,3,5,13} 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 only 73.5% of centers but when interviewed the cold chain handlers said that the diluents were stored in ILR at least 24 hours before use.

VVM concept conceived in 1997 was formally introduced for all UNICEF procured OPV vials in 1996 and slowly expanded to other heat sensitive vaccines.¹⁷ 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 about 97.1% of the centers, the vaccines were in usable condition i.e. in stage-1 and stage-2. Similar results were reported from various studies where vaccines were in usable condition.^{8,16,18}

In our study, all the cold chain handlers had correct knowledge of temperature to be maintained in ILR but 84% them did not know the right temperature to be maintained in DF. Cold chain assessment in Chattisgarh revealed that overall 45% of the staffs were aware of the correct vaccine temperature norms.¹⁹ Naik et al in their study showed that one-fourth and four-fifth of the vaccinators knew the exact temperature range for DF and ILR respectively.¹⁵

Conditioning of ice packs is important to be ensured before using the icepacks for use in vaccine carrier

during the immunization session or pulse polio programme or during outreach immunization session to prevent freeze-sensitive vaccines from freezing.¹ But in our study only 54% of cold chain handlers had knowledge about conditioning of ice packs. However, knowledge and actual practice of conditioning of ice packs is best done by observation during the actual immunization session. Conditioned icepacks were found in 80% sites in Mamta Diwas study.¹²

LIMITATIONS OF THE STUDY

This study being a cross-sectional study, cold chain practice during the actual immunization sessions were not evaluated. Secondly, this study does not include testing of vials for vaccine potency. Here VVM status and examination of frozen state of the vaccine were used as proxy measure of vaccine potency.

CONCLUSION

In the process of strengthening immunization services in the state, the availability of cold chain equipments has improved with 84% and 63% of the health centers in BBMP area having ILR and deep freezer respectively. Cold storage practice was good/ fair in 88% of the centers. Knowledge of cold chain handlers regarding DF's temperature (14%), conditioning of ice packs (54%) and thermostat adjustment (75%) was low. Relevant training for those handling the cold chain with continuous supportive supervision is recommended. Strengthening immunization services will not only include the cold chain equipment availability but also the right attitude and practice of cold chain handling by the cold chain handlers.

Recommendations: Though all the cold chain handlers were trained in the last one year, re-training/refresher sessions are of utmost importance to keep them on track. Regular onsite monitoring and demonstration of correct cold chain practices will strengthen their knowledge and practice regarding cold chain. Ensuring supply of thermometers and other cold chain equipments is one of the crucial activities to monitor cold chain.

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