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Evaluation of Vaccine Cold Chain in Urban Health Centers of Municipal Corporation of Surat City, Western India

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ABSTRACT

Background: The success of immunization depends highly on the level of cold chain maintenance. The aim of the study was to assess the condition of cold chain equipment, practices adopted for cold chain maintenance and knowledge of the vaccinators.

Methods: It was a cross-sectional study conducted in 20 UHCs of Surat Municipal Corporation (SMC). Cold chain equipment were observed with regards to their condition, along with the practices adopted by vaccinators for cold chain maintenance. A pre-designed and pre-tested questionnaire was used to interview the vaccinators regarding their knowledge and awareness regarding cold chain practices, management and handling. Data were entered and analyzed using Epi Info v 3.5.1. Simple proportions were calculated.

Results: Absence of separate stabilizer for deep freezers and ILRs (85%), ill-maintained temperature-record register, lack of criss-cross pattern of ice packs in deep freezer (65%), presence of things other than ice packs in deep freezer (10%) and things other than vaccines in ILR (10%) indicate poor cold chain maintenance. In addition to this, expired vaccines in ILR (5%), vaccines in the "unusable" stages of VVM (15%), lack of emergency contact number nearby in case of cold chain failure (85%), lack of inverter (85%), lack of generator (85%) and failure to note time of reconstitution on the vaccine vial at the time of vaccination (25%) indicate poor cold chain practices. Lack of knowledge of defrosting of ILR and deep freezer (45%), lack of knowledge about Shake test (40%), lack of knowledge of temperature range to be maintained in deep freezer (70%) and in ILR (15%) indicate poor knowledge of vaccinators.

Conclusion: Cold chain maintenance and practices need improvement. Knowledge of vaccinators was overall unsatisfactory.

Keywords: Cold chain maintenance, cold chain practices, knowledge of vaccinators

Original Article

INTRODUCTION

Immunization is one of the best efforts that India is putting forward currently to fight against various vaccine preventable

diseases.[1] India had started its Universal Immunization Program (UIP) in 1985 focusing more on infants and pregnant mothers.[2] The country spends a lot of money every year on immunization.[1] The success of this program depends highly on the level of cold chain maintenance of the vaccines right from the site of manufacturing up to its administration.[1] Urban Health Centers (UHCs), set up under various Municipal Corporations, have been the backbone for delivering services related to immunization in urban areas in India. It is thereby important that cold chain system be adequately maintained at these centers. It is repeatedly found that cold chain is not maintained properly in India.[3-6] Health workers involved in immunization are also part of the cold chain system.[4] Therefore, good knowledge of these health workers in the maintenance of the cold chain system is a pre-requisite in the correct delivery of immunization services. It is also imperative that the condition of cold chain equipment, i.e., deep freezer and ice-lined refrigerator (ILR) is maintained appropriately and emergency plan in case of cold chain failure is followed adequately.[1] This study also attempted to evaluate the loop holes in the maintenance of cold chain of vaccines and assessed the knowledge and practices adopted by the vaccinators for the same in Surat city, Western India.

METHODS

Study design and setting: Surat, situated 270 km north to Mumbai, is the fourth fastest growing city in the world.[7] Better known as the diamond city, Surat has seen a lot of urbanization in recent years. The total population (both rural and urban) of Surat city has increased from 49.95 lakhs in 2001 to 60.79 lakhs in 2011 according to Census data.[8,9] Surat Municipal Corporation has been working incessantly for improving the overall health of the citizens of Surat. The city has a network of 36 UHCs under SMC in a total of 7 administrative zones. The zone-wise population of Surat city according to Census 2001 data is given in Table 1[10].

Each UHC has a designated vaccinator who looks after the vaccine cold chain system and the activities related to immunization. A cross-sectional study was conducted in 20 UHCs of Municipal Corporation of Surat city.

Sample size and sampling design: As data from any prior study in Surat was not available, we have included at least 50% of the UHCs of SMC in our study. Thus, out of 36 UHCs, we decided to include 20 UHCs for our study. At least 50% of health centers were selected from each zone so as to make suitable representation of all the health centers of the city. One maternity home from each zone was deliberately selected as it was considered as a higher center providing emergency obstetric care together with primary health care. In each zone, the remaining UHCs (non-maternity) were selected randomly by lottery method. Thus, 20 health centers were selectedas shown in Table 2.

Data collection: Permission for carrying out the study was obtained from the Medical Officer of Health (MOH) of SMC. Data collection was carried out from June 2011 to July 2011. In this study, cold chain equipment was observed by the researchers, with regard to their condition and practices adopted by vaccinators for cold chain maintenance. The alternatives available in the UHC in case of cold chain failure were also assessed. A vaccination session was observed to assess the cold chain practices at the

Table 1: Zone-wise distribution of urban population of Surat city according to Census (2001)

Seven zones of SMC	Population
East zone	711,516
West zone	287,144
North zone	416,370
South zone	407,980
Central zone	413,641
South west zone	242,466
South east zone	397,257
Total urban population	2,876,374

SMC=Surat municipal corporation

Table 2: Selection of UHCs from 7 administrative zones

ZONE	Total number of UHCs	Number of selected UHCs
Central zone	9	5
West zone	2	2
South zone	5	2
South west zone	4	2
East zone	5	3
North zone	5	3
South east zone	6	3
Total	36	20

UHCs=Urban health centers

time of vaccination. A pre-designed and pre-tested questionnaire was used to interview the vaccinators regarding their knowledge and awareness of cold chain practices, management and handling. We assessed the knowledge of the vaccinators on a 3-pointer scale with those knowing exactly (exactly in its stated form), knowing but not properly (not exactly in its stated form, but having the concept behind it) and those who had not heard anything about the point in question. The questionnaire was pre-tested in 2 UHCs selected purposively out of the remaining 16 UHCs not included in the study. Changes were made in the questionnaire accordingly after discussing the issues that we came across in the pilot study.

Statistical analysis

Data were entered and analyzed using Epi Info v 3.5.1. Simple proportions were calculated.

RESULTS

In all the 20 health centers, ILR and deep freezers were observed separately. The observations with regard to deep freezers and ILR are tabulated in Tables 3 and 4.

In this study, a separate voltage stabilizer was attached each to deep freezer and ILR in 3 (15%) health centers. Deep freezers were exposed to sunlight in 2 (10%) health centers. It was refreshing to find that in our study, temperature was being recorded twice a day for both deep freezer and ILR in all the health centers. Information regarding defrosting of deep freezers and ILRs was recorded on the temperature-record register in 10 (50%) health centers. Thickness of ice on the side walls was >5 mm in the deep freezers and ILRs of 10 (50%) health centers. It was also found that ice packs were arranged in a criss-cross manner in only 7 (35%) health centers. The present study found water bottles kept inside deep freezer in 2 (10%) health centers. And, at 2 (10%) health centers, things other than vaccines/diluents, like empty water bottles, were kept inside the ILR. Vaccines were arranged according to temperature sensitivity in ILR in 14 (70%) health centers.

On observing the alternatives to cold chain failure (n = 20), we noticed that emergency contact number was written in the same room nearby in only 3 (15%) health centers. We found that 3 (15%) UHCs each had either a working inverter

Table 3: Observations related to deep freezer and ILR (n=20)

Observations of cold chain equipment	Deep freezer (%)	ILR (%)
Working cold chain equipment available	20 (100)	20 (100)
Lack of separate stabilizer attached with equipment	16 (80)	17 (85)
Not placed on wooden block	6 (30)	6 (30)
Not placed at least 10 cm away from wall	1 (5)	1 (5)
Exposure to direct sunlight at any time in the day	2 (10)	0 (0)
Properly working thermometer available	19 (95)	20 (100)
Record of temperature maintained twice a day in separate register	20 (100)	20 (100)
Lack of signature of person recording temperature for each record	17 (85)	18 (90)
Lack of information on defrosting recorded on temperature chart	10 (50)	12 (60)
Lack of cross-check signature of medical officer	11 (55)	11 (55)
Thickness of ice on side walls >5 mm	10 (50)	11 (55)
Anything other than ice packs kept in deep freezer	2 (10)	-
Ice packs not kept in criss-cross pattern in deep freezer	13 (65)	-

ILR=Ice-lined refrigerator

Table 4: Observations related to ILR (n=20)

Ice-lined refrigerator	Yes (%)
Anything other than vaccines or diluents kept	2 (10)
Diluents not kept at least 24 hours before use	3 (15)
Different vaccines not kept in different boxes	1 (5)
Vials not kept in plastic/glass container	11 (55)
Lack of proper arrangement of vaccines (according to their sensitivity)	6 (30)
T series and HB vaccines touching the wall of ILR	4 (20)
Presence of expired vaccines	1 (5)
Presence of stage 3 or 4 vaccines	3 (15)
Opened or used vaccines available	1 (5)
Presence of frozen vaccines (verified by Shake test)	1 (5)
Stock register of vaccines available	19 (95)
Stock register not properly maintained	3 (15)

ILR=Ice-lined refrigerator

or a generator. Though, an alternate working refrigerator was available in 13 (65%) health centers.

On observing the vaccination sessions (n = 20), we found that the vaccinators were reading VVM at the time of vaccination at 13 (65%) health centers. The time of reconstitution was noted on the vaccine vial by the vaccinator at 15 (75%) health centers. The reconstituted vaccine was discarded after the recommended time limits in 19 (95%) health centers.

Table 5 shows the knowledge of the vaccinators regarding cold chain. It was good to see that 15 (75%) vaccinators knew the definition of cold chain exactly in its stated form, whereas 5 (25%) did not know it exactly. It was encouraging to see that 18 (90%) vaccinators knew the full form of VVM and stages of VVM correctly. It was reassuring to see that almost all (95%) vaccinators knew the correct arrangement of vaccines in the ILR according to temperature sensitivity. Knowledge of the vaccinators regarding the timing of defrosting of ILR and deep freezer was poor, with only 11 (55%) knowing exactly, the criteria for defrosting. It was found in the present study that 12 (60%) vaccinators knew exactly about Shake test. Only 5 (25%) vaccinators knew the exact temperature range for deep freezer, though, 16 (80%) knew the exact temperature range for ILR. On being asked about the steps incumbent to refrigerator failure, 8 (40%) vaccinators told to put the vaccines in cold boxes; 5 (25%) told to put it in alternate storage refrigerator; 5 (25%) told to use the generator; 1 (5%) told to call the higher authority and 1 (5%) told to shift the vaccines in a nearby ice-cream vendor's refrigerator.

DISCUSSION

Observations of ILR and deep freezer

A separate voltage stabilizer should be attached each to deep freezer and ILR, except in emergency, when one stabilizer per two small equipment is acceptable.[1] The function of the voltage stabilizer is to monitor the range of fluctuations in the main voltage of 90-280 V and maintain voltage in a required range of 220 + 10 V.[1] Stabilizer protects the cold chain equipment against voltage fluctuations and is an essential pre-requisite.[1] The present study claimed that a separate voltage stabilizer was attached each to deep freezer and ILR in only 15% of the health centers. A shortage of voltage stabilizers was also reported in several other studies.[11-13] Medical Officer of the respective UHCs should ensure adequate supply and maintenance of voltage stabilizer and report to higher authority in case scarcity persists.

Deep freezer and ILR should be placed in such a way in the room that they are not exposed to sunlight any time during the day.[1] Exposure to

Table 5: Knowledge assessment of vaccinators regarding cold chain (n=20)

Question	Know exactly (%)	Know but not exactly (%)	Don't know (%)
Definition of cold chain	15 (75)	5 (25)	0 (0)
Knowledge of VVM	18 (90)	2 (10)	0 (0)
Knowledge of arrangement of vaccine in ILR according to temperature sensitivity	19 (95)	1 (5)	0 (0)
Knowledge of what should be kept in ILR	20 (100)	0 (0)	0 (0)
Knowledge of what should be kept in deep freezer	20 (100)	0 (0)	0 (0)
Knowledge of the proper location for ILR and deep freezer	18 (90)	2 (10)	0 (0)
Knowledge of the timing of defrosting for ILR and deep freezer	11 (55)	8 (40)	1 (5)
Knowledge of the method to check frozen vaccine (Shake test)	12 (60)	6 (30)	2 (10)
Knowledge of the number of times the temperature to be recorded in a day for ILR and deep freezer	19 (95)	1 (5)	0 (0)
Knowledge of the temperature of ILR	16 (80)	3 (15)	1 (5)
Knowledge of the temperature of deep freezer	5 (25)	14 (70)	1 (5)

ILR=Ice-lined refrigerator

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 temperature of the vaccines in ILR and ice packs would not be prepared in deep freezer. The present study stated that deep freezers were exposed to sunlight in 2 (10%) health centers. This finding was similar to a study by Sachdeva, *et al.* which reported that the cold chain equipment were kept away from sunlight in all the health centers.[12]

The temperatures in the ILR and deep freezer must be monitored twice daily.[1] 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.[1] The ILR and deep freezers each should have a separate thermometer and temperature record book.[1] It was refreshing to find that in our study, temperature was being recorded twice a day for both deep freezer and ILR in all the health centers in separate temperature record books. This was more than what Mallik, *et al.* (60%) and Sachdeva, *et al.* (71.87%) found in their studies.[12,13] Also, in the present study, working separate thermometers were found in deep freezer in 95% health centers and in ILR in all the health centers.

The temperature in the ILR/freezer can rise if there is a thick layer of ice around the freezer or along the walls and bottom of ILRs.[1] It is therefore necessary to defrost them periodically. This should be done if the ice in the freezer is >5 mm thick.[1] The present study showed that information regarding defrosting of deep freezers and ILRs was recorded on the temperature-record register in only half of the health centers. Thickness of ice on the side walls was >5 mm in the deep freezers and ILRs of half of the health centers. This was more than that shown by Sachdeva, *et al.* (37.5%), though they kept the cut-off for thickness >6 mm.[12] This suggests lack of regular defrosting by the cold chain handlers, which need to be improved and monitored subsequently by the Medical Officer of the respective UHC.

Ice packs should be stacked on the floor of the deep freezer horizontally (not flat) on its edge by keeping 1-2 mm space from each other for air circulation, in a criss-cross manner.[1] Yet, in our study, we found this in only one-third (35%) of the health centers. This was probably due to the increased demand of ice packs in health centers, especially during Sub-National Immunization Day (SNID) rounds, which are frequently conducted in urban areas of Surat city. The requirement for a large number of ice packs can be easily met with proper planning like transferring around 50 ice packs into a large cold box. Fifty more ice packs can be frozen in two days and continuing the procedure till the required number of ice packs are frozen.

Deep freezers should be used to prepare and store ice packs only; UIP vaccines should not be stored in it.[14] In spite of these guidelines, in our study, we found water bottles kept inside deep freezer in 2 (10%) health centers. It is customary, not to keep other drugs and vaccines not used in UIP, in ILR.[1,14] In our study, at 2 (10%) health centers, things other than vaccines/diluents, like empty water bottles, were kept inside the ILR. This was much less than what Sachdeva, *et al.* claimed in their study (53.12%).[12]

Vaccines lose their potency due to exposure to excessive heat or excessive cold. OPV and measles vaccines can be kept at bottom of the basket while BCG, DPT, DT and TT vaccines should be kept in upper part of the baskets.[1] In our study, we found that the vaccines were arranged accordingly in more than two-third of the health centers. This was similar to what Sachdeva, *et al.* stated in their study that heat-sensitive vaccines were stored correctly in all, while, freeze-sensitive vaccines were stored correctly in 62.5% health facilities only.[12] Vaccinators need to understand the importance of this arrangement, as impotent vaccines give a false sense of security against diseases, which a child would contract later on despite the vaccination.

Observations related to alternatives to cold chain failure

The present study found that emergency contact number was written nearby in the same room in only 3 (15%) health centers. Mallik, *et al.* argued in their study that no organization maintained a chart in case of cold chain failure.[13] Samant, *et al.* showed generator facility in 65% of PHCs.[15] This is in contrast to our study, where we found 30% UHCs had either a working inverter or a generator. Though, an alternate working refrigerator was available in just less than two-thirds of the health centers. The cold chain is dependent on electrically operated machines on which one cannot depend

completely. Alternative storage locations will have to be identified in advance.[1] Suitable posters should be designed and pasted on machines with clear instructions in local languages on how to handle such emergency situations, especially during electricity failure.[1] It would be prudent to identify more than one alternative at each UHC for tackling the situation.[1]

Observations of vaccination sessions

On observing the vaccination sessions (n = 20), we found that the vaccinators were reading VVM at the time of vaccination at 13 (65%) health centers. The time of reconstitution was noted on the vaccine vial by the vaccinator at 15 (75%) health centers. The reconstituted vaccine was discarded after the recommended time limits in 19 (95%) health centers. Reconstituted BCG and measles vaccines should not be used beyond 4 hours from the time of its reconstitution.[1] This increases the chances of AEFIs (Adverse Effect Following Immunization).[1] If not utilized completely, these reconstituted vaccines should be discarded within 4 hours in the case of BCG and measles.[1]

Knowledge of vaccinators

It was good to see that three-fourth of the vaccinators knew the definition of cold chain exactly in its stated form, while one-fourth of the vaccinators knew the concept behind it suggesting that they were aware of cold chain. Most of the vaccinators knew the full form of VVM and stages of VVM correctly, suggesting that VVM is now a matter of common knowledge for the vaccinators. Thakur, *et al.* also highlighted similar results with 94.4% staff members being aware that VVM is present on vaccine itself and 71.7% knowing how to read it.[4] Almost all vaccinators knew the correct arrangement of vaccines in the ILR according to temperature sensitivity. This was in contrast to what Mallik, *et al.* reported, that vaccinators had poor knowledge of heat sensitive vaccines.[13]

Knowledge of the vaccinators regarding the timing of defrosting of ILR and deep freezer was poor, which needs improvement. Shake test, for testing whether a vaccine is frozen or not, should be a matter of common knowledge for the vaccinators. But, we found in the present study that just less than two-thirds of the vaccinators knew exactly about Shake test. It is imperative that vaccinators are well conversant with the temperature range to be maintained in ILR and deep freezer so that a break in cold chain can be easily detected and reported to the higher authority. In the present study, only one-fourth of the vaccinators knew the exact temperature range for deep freezer. Though, four-fifth of them knew the exact temperature range for ILR. Yuan, *et al.* found in their study that 57.3% individuals correctly specified the optimal temperature range for vaccine storage.[16] Ortega Molina, *et al.* found in their study that 61.43% knew the optimal temperature range.[17] Jeremijenko, *et al.* reported that educating a staff member on correct vaccine storage conditions and nominating that person to be responsible for monitoring refrigerator temperatures improves adherence to vaccine storage guidelines.[18]

On being asked about the steps incumbent to refrigerator failure, more than one-third of vaccinators told to put the vaccines in cold boxes, one-fourth told to put it in alternate storage refrigerator, one-fourth told to use the generator, 5% told to call the higher authority and 5% told to shift the vaccines in a nearby ice-cream vendor's refrigerator. Irrespective of the step that is followed in case of refrigerator failure by the vaccinators, a fixed and pre-decided plan of action should be individualized for each UHC.

CONCLUSIONS

Cold chain maintenance and practices were not up to the mark in the UHCs of SMC. Knowledge of vaccinators was overall unsatisfactory.

The present study contemplates for periodic refresher training and capacity building for cold chain maintenance of all the cold chain handlers. Medical Officers should be actively involved in the monitoring and supervision of the cold chain system.

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