

Original Research Article

Evaluation of cold chain and logistics management practice in Durg district of Chhattisgarh: pointer from Central India

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ABSTRACT

Background: Immunization is the effective method of preventing childhood diseases. One of the important elements for improving the immunization is cold chain and vaccine logistics management which are the left and right hands of immunization programme. Keeping this in mind, the present study was done with the objectives a) to ascertain the status of cold chain equipment and logistics management using GOI monitoring format and b) to ascertain the awareness and practice of cold chain handlers about cold chain equipment and logistics management in Durg district of Chhattisgarh, India.

Methods: A cross sectional study was conducted among randomly selected 20 cold chain points (CCPs) of Durg district using standard GOI structured questionnaires.

Results: Out of 20 cold chain points (CCPs), 20% CCPs, vaccine were found in frozen state. Functional thermometer was available in 75% CCPs, out of which 65% had temperature in the recommended range. Twice daily recording of temperature was found only in 95 % CCPs. Record of power failures and defrosting was noted in temperature log books in 70% CCPs. The correct placement of ice packs inside Deep freezer was observed in only one CCPs. T-series vaccine vials were placed properly in ILR in 85% CCPs. With respect to knowledge on freeze sensitive vaccine and shake test, 74 % and 53% of cold chain handlers had correct knowledge.

Conclusions: The quality of immunization programme can be increased by proper maintenance of cold chain and management of vaccine logistics at every designated cold chain points. There is need to improve the knowledge level of CCHs regarding cold chain maintenances and handling practices.

Keywords: Cold chain, CCPs, CCE, Cold chain maintenances

INTRODUCTION

India has one of the largest immunization programme in the world.¹ In 1974, WHO launched a global immunization programme, known as Expanded Programme on Immunization (EPI) to protect all children against six vaccine-preventable diseases and the government of India launched EPI in the year 1978. Vaccination has been the most effective preventive strategy to control infectious diseases.² Immunization is

one of the safest and most effective methods of preventing childhood diseases. It is a key strategy to child survival which significantly lowers morbidity and mortality rates in children.³ According to NFHS-3 (2005-06), reports only 43.5% of children in India received all of their primary vaccines by 12 months of age.⁴ Despite the concerted efforts of the Government and other health agencies, approximately 10 million children in India remain unimmunized. India has the highest number of such children in the world.⁵ The Ministry of Health and

Family Welfare; Govt. of India launched Mission Indradhanush in December 2014 as a special drive to vaccinate all unvaccinated and partially vaccinated children under UIP. The mission focuses on interventions to improve full immunization coverage in India from 65% in 2014 to at least 90% children in the next five years. This will be done through special catch-up drives.⁶ One of the important elements for improving the immunization is cold chain and vaccine logistics management which is the backbone of immunization programme.¹ Success of national immunization programme is highly dependent on supply chain system for delivery of vaccines and cold chain equipments, with a functional system that meets 6 rights of supply chain. The right vaccine in the right quantity at right place at the right time in the right condition and at right cost.² The Cold Chain is a system of storing and transporting vaccines at recommended temperatures from the point of manufacture to the point of use.⁵ The cold chain system is necessary because vaccine may be ineffective due to failure of cold chain system.² If vaccine is exposed to too much heat, light or cold, it can be damaged and lost its potency or effectiveness.³ Once vaccine potency is lost it cannot be restored and it becomes wastes.⁵ So, care must be taken to see that the vaccines do not lose their potency, before the date of expiry by maintaining 'Cold chain'. All vaccines retain their potency at temperature between +2°C to +8°C.⁷ With this background, this study was carried out with the following objective

- To ascertain the status of cold chain equipment and logistics management using GOI monitoring format in Durg district.
- To ascertain the awareness and practice of cold chain handlers about cold chain equipment and logistics management in Durg district of Chhattisgarh.

METHODS

This was a cross sectional study done during Mission Indradhanush supported by UNICEF Chhattisgarh in Durg district in the month of October 2015. This study was a part of project of Strengthening Routine Immunization programme done by Community Medicine Department of Pt. JNM Medical College Raipur. The faculties, PG scholars were involved in data collection as a team member in this study. Durg is district in central part of the Chhattisgarh plain in Durg Division of Chhattisgarh with an area of 8,535 km² and population of 3,343,872 (census 2011). Durg district has one district hospital, 8 Community health centres and 28 Primary health centres. There are 26 functional Cold Chain Points in this district. 20 cold chain points were evaluated randomly by the investigator and physical verification of the available cold chain equipments was done using predesigned pretested checklist. Cold storage monitoring was assessed by actual documentation at various levels of

cold chain infrastructure and logistics. Availability of alternate plan in event of electrical failure was verified at the time of visit. All vaccines were inspected for expiry date, frozen state and VVM (vaccine vial monitoring) status and open vaccine vial storage policy as per GOI guidelines. Training status and knowledge of the all available cold chain handlers were also checked by the survey team. Data was collected and compiled using MS Excel and represented in percentage and proportions.

RESULTS

Among all CCPs visited only 40% (8 out of 20) had dedicated space/room and 75% (15 out of 20) had dedicated space for syringes and diluents. Only one CCP had correct placement of ice-packs inside DFs moreover 55% of CCPs ice packs were filled with water up to the mark over ice packs. Among all visited CCPs 45% (9 out of 20) dedicated table/space for conditioning and clean cloth was available at 55% (11 out of 20) CCPs for the same (Table 1). It was observed that 75% (15 out of 20) had thermometer in functional state. Out of this only 66.67%, 10 out of 15 thermometers were placed in correct position within ILR and DFs among visited CCPs. Temperature log book were maintained in almost all the CCPs. But record of power failure was maintained in 30% (6 out of 20) CCPs. Defrosting and cleaning records were maintained in 25% of CCPs. We also observed that Temperature Logbook was supervised by District Immunization Officer in only 10 % (2 out of 20) in last three months (Table 2). It was observed that only 13 out of 20 (65%) visited CCPs, cabinet temperature of Ice Lined Refrigerator (+2°C to +8°C) and DFs (-15°C to -25°C) was maintained (Table 2). Heat sensitive vaccine (i.e. Hep B / T series vaccines) were kept in top of the ILR in 65% (17 out of 20) CCPs (Table 3). Out of all visited CCPs, 3 were out of stock for measles, 1 for BCG and 1 for OPV. In 20% (4 out of 20) CCPs vaccine were found in frozen state (Table No. 4). All CCPs designated Cold Chain Handlers were in place (i.e. ANM, Staff Nurse or Pharmacist) except one CCP where no designated person was available for such purpose. As far as knowledge of cold chain handlers is concerned, 14 (73.48%) had knowledge about all freeze sensitive vaccines and only 10 (52.63%) had complete knowledge about "Shake Test" (Table 5). 70% (14 out of 20) CCPs open vials were correctly (i.e. separate box/zipper bag) placed inside ILR with date and time mentioned in it (Table 6). Out of all visited CCPs 15 had internet facility out of which 10 were found in working condition. 25% (5 out of 20) CCPs were enrolled in National Cold Chain information system 90% (18 out of 20) of CCPs had stock register in place out of which only 66% (12 out of 18) centers had updated records of vaccine and the logistics. 80% (16 out of 18) CCPs did not documenting the records of expired and waste vaccine. Charts/SOPs for operating of ILR/DFs were available in 60% of centers. Majority of the centers (80%) did not have visible emergency or contingency plan (Table 7).

Table 1: Distribution of cold chain infrastructure in CCPs of study area.

Cold chain infrastructure	Yes (N=20)	%
Dedicated Room / space available for Cold Chain	8	40
Dedicated Room/space available for Syringes and Diluents (Dry storage).	15	75
Correct placement of icepacks inside Deep Freezer for freezing (criss-cross manner)	1	5
Icepacks kept for freezing filled up to the mark and capped.	11	55
Dedicated table / space available for conditioning of Ice-packs	9	45
Clean cloth available for wiping of Icepacks after conditioning.	11	55

Table 2: Distribution of vaccine and diluents storage practices in side ILR in CCPs of study area.

Vaccine and diluents storage practices	Yes (N=20)	%
Separate functional thermometer inside every functional equipment	15	75
Separate functional thermometer placed correctly (n=15)	10	66.67
Each CCE is having separate temperature log book	9	45
Temperature is recorded twice daily	19	95
Temperature is recorded on Sundays and holidays	16	80
Record of power failure maintained in temp. log book	6	30
Records of defrosting / cleaning maintained in Temp.log book	5	25
Temp. Log book reviewed by DIO in last three months	2	10
Functional ILR within the temperature range (+2°C to +8°C)	13	65
Functional Deep freezer within the normal temperature range	13	65

Table 3: Distribution of vaccine and diluents storage Practices in side ILR in CCPs of study area.

Vaccine and diluents storage practice	Yes (N=20)	%
Only UIP vaccines are placed inside ILR?	19	95
The diluents are stored inside the ILR from the time of receipt	13	65
Diluents are stored inside ILR 24 hours before the session	7	35
Diluents are never kept in the ILR till issue for session	0	00
Vaccines are stored in ILRs		
Within Basket	19	95
Over 2 rows of empty ice packs	0	00
Directly on the floor of ILR	1	5
T-series / Hep-B vaccines stored in the top of the ILR	17	85

Table 4: Distribution of vaccine and other stock availability in CCPs of study area.

Stock availability	Yes N(20)	%
Nil stock of any vaccine found during the visit.	3	15
All the vaccine vials have proper readable labels	19	95
All the vaccines found within expiry dates	19	95
All the vaccines with usable VVM	20	100
Any vaccine found in frozen condition	4	20
Any opened vaccine vial is stored inside ILR*	14	70

Table 5: Knowledge of cold chain handler in CCPs of study area.

Knowledge of cold chain handler	Yes (N=19)	%
Knowledge of Cold Chain Handler about all freeze sensitive vaccines	14	73.68
Complete knowledge of Cold Chain Handler about “Shake test”	10	52.63
Cold chain handlers trained in last 3 years on Cold Chain Module.	19	100

Table 6: Adoption of open vial policy in CCPs of study area.

Open vial policy	Yes (N=14)	%
Opened vaccine vials are stored in separate box / zipper bag	13	92.86
Date and time of opening is written on the vial	8	57.14
All opened vaccine vials are of < 28 days duration, since opened?	13	92.86

Table 7: Management information system, information education and communication and supporting management in CCPs of study area.

Functions	Yes	%	
The centre has got independent Internet connection,(n=20)	15	75	
Is the internet connection working on the day of visit?(n=15)	10	50	
NCCMIS for this Cold Chain Point is complete?(n=20)	5	25	
CCT visited this Cold Chain Point for Preventive Maintenance in the last quarter? (n=20)	12	60	
Is stock register in use for vaccine and logistics as per norm? (n=18)	15	83.33	
All parameters for vaccines, logistics and diluents are recorded?(n=18)	12	66.66	
Returned vials from the field are entered in the stock register?(n=18)	11	61.11	
Is distribution register in use for vaccine and logistics as per norm? (n=18)	13	72.22	
Expired and wasted vaccines are documented in Stock register?(n=18)	4	22.22	
Physical counting of vaccine stock is done at least once in last 3 months? (n=18)	16	88.88	
Physical stock of (BCG / Measles) is matching the stock register for that day? (n=18)	12	66.66	
System in use for vaccine & logistics stock management. (n=18)	Paper	18	100
	Excel	0	00
	Web	0	00
Vaccine & Logistics stock management updated till last transaction.(n=18)	11	61.11	
CCT Tour plan for previous 3 months is available.(n=18)	0	00	
Does the CCT tour plan covers all the Cold Chain Points in the district.(n=18)	0	00	
Chart / SOP on ILR / DF / Vaccine / Ice pack arrangements available(n=20)	12	60	
Emergency / Contingency plan visible(n=20)	4	20	

DISCUSSION

Immunization is one of the most cost effective strategy in reducing childhood morbidity and mortality.² Immunization has to be sustained as a high priority to further reduce the incidence of all VPDs. cold chain and vaccine management is one of the essential components for improving quality of immunization services.¹ Careful attention to storage and handling is essential to ensure optimal potency of vaccines to maximize the resulting efficacy of vaccination.⁸

Temperature of ILR /DF used for storage of vaccines must be recorded twice daily. The ILR and DF each should have separate thermometer and temperature record book.¹ The present study showed that only 15 (75%) CCPs, separate functional thermometer was available inside every functional equipment and among these only 10 (66.67%) CCPs, thermometer were placed in correct position within functional ILRs/DFs. In a similar study done by Biradar et al at Bijapur Karnataka found that only 76. 1% health centre, functional thermometer were placed inside every ILRs and DFs.⁹ A study done by Govani et al in all urban health centers of Ahmadabad

Municipal Corporation revealed that in 85% ILR and 83% DFs , functional thermometer were properly placed.¹⁰ The findings in our study was much less than that what Naik et al claimed in their study that working separate thermometers were found in DFs in 95 % health centers and ILR in all the health centers.¹¹

The present study stated that among, all CCPs, only 9 (45 %) had separate temperature log book for ILR and DF in comparison to study done by Roa et al observed 94.2% centers.¹² The findings in our study was more than that what Mallik S et al (60%), Samath et al (65%) and Sachdeva et al (71.87%) found in their studies.¹³⁻¹⁵ The present study revealed that there was poor documentation of records of power failure only in 30% CCPs. This observation was almost similar to (33%) study done by Gupta A et al and contrast to study of Govani KJ et al who reported 12.5%.^{10,16} Similar studies by Goel NK et al, Santosh M⁹ et al Bijapur Karnataka and Mallik S et al, where these observations were even high as 80%, 65% and 41% respectively.^{9,13,17} Defrosting and cleaning status (25% of CCPs) while only in 2 (10%) CCPs, Monitoring of temperature log book was done by District Immunization Officer in last three months it was quite low in comparison to studies done by Gupta A et al (100

%), Govani KJ et al (89%), Santosh M et al (86.9%) and Goel NK et al (95.3%).^{9,10,16,17} The potency of vaccine depends upon maintaining vaccines at right temperature (i.e. +2°C to + 8°C), Although it is not an easy task but the consequences of not doing the same can be disastrous. In our study 65% (13 out of 20) CCPs had the cabinet temperature of ILR and DF was in the recommended range at the time of visit. Our observations corroborates the finding of other researchers in a similar study of Kumar H et al observed 69.75%, Samant et al reported 75% and Mallik et al observed 80% centers and by Krishnappa et al revealed that in 74.2% ILR and 53.3% DF temperature was within recommended range.^{13,14,18,19} As per the vaccine logistic management guidelines, all vaccine must be kept in a basket and if basket not available, keep 2 layer of empty ice pack laid flat on the floor of ILR. OPV and measles are kept at the bottom of basket while BCG, Pentavalent, DPT and TT vaccines are kept in upper part of the baskets. In our study, we found correct placement of vaccine inside ILR was in 85% (17 out of 20) CCPs. In a similar studies, Gupta et al, Santosh M et al, Tushar Patel et al, Sharma et al and Naik AK et al, highlighted same observations in 66.6%, 84.8%, 93.2%, 90%, and more than two third of CCPs respectively.^{9,11,15,20,21} As per the guidelines, ice packs need to be stacked in criss cross manner inside deep freezer which allows space for air circulation to make a frozen ice packs to maintain the recommended level of temperature at point of vaccination. Our study reveals that 95% (19 out of 20) of CCPs had faulty arrangements of ice packs inside Deep Freezer. Above observations were coated by different authors as by Santosh M et al in 73.9% Goel NK et al in 100% and both Naik AK et al and Gupta A et al in one third of CCPs respectively.^{9,11,16,17} Ice packs are key components of cold, used for inside lining of cold boxes and vaccine carrier at facility and at field respectively for vaccine storage and transport at storage. The water should be filled only up to the level mark on the side and cork should be tight so that there is no leakage. Only in 55% CCPs (11 out of 20) were following these practices among all visited sites. Conditioning of ice packs is an important component to prevent freeze sensitive vaccine from freezing during immunization session or outreach session. We observed that 9 (45%) CCPs had dedicated space for conditioning of icepack and 11 (55%) CCPs had clean cloth for wiping icepacks for the same purpose. In other study done by Sharma DK et al 80% site had conditioned icepacks in Diwas M.²¹ As per the guidelines, diluents are to be stored in ILR. If there space constraint, it can be stored outside the ILR. But they need to keep in ILR for at least 24 hours before vaccination because vaccines and diluents should be of similar temperature during reconstitution. In our study these guidelines were adopted in 35% (7 out of 20) CCPs where as other researchers reported 93.5%, 100%, 73.5% by Santosh M et al, Gupta A et al, Krishnappa et al respectively which was quite high in comparison to our observation.^{9,16,19} Our study highlights the fact that 75% of CCHs knew about all freeze sensitive vaccines which was quite low in

similar study done by Mallik et al and Ortega Molina P et al.^{13,22} Our study depicts that CCHs of 50% CCPs (10 out of 20) knew about shake test. Shake test done for testing whether vaccine is frozen or not. Other researcher Naik AK et al, Gupta A et al and Roa S et al reported the same observation among two third, 66.66% and 22.4% of CCHs respectively.^{11,12,16} In 1966, VVMs were introduced on oral polio vaccine. Their use was the extended to all expanded program on immunization (EPI) vaccines. VVM, a time temperature indicator that accumulates information on the exposure of a given vaccine vial to heat and temperature, has allowed vaccinators to use vaccines. In our study, all CCPs (100%) vaccines were in usable condition (i.e. stage I and stage II). Similar results were reported from various other studies where vaccines were in usable condition (i.e. stage III and stage IV).^{14, 19, 20, 23} In 3 CCPs, there was nil stock of vaccine like BCG, OPV was found during visit. In 19 CCPs (95%) vaccines were found within expiry dates except in one (5%) CCP, similar result was obtained in study done in Surat city.¹¹ In 20% (4 out of 20) CCPs, vaccine were found in frozen condition. This observation was high in comparison to study done by Naik AK et al reported 5% of centers had similar findings.¹¹ In present study, 14 (70%) CCPs, open vaccine vial were stored inside ILR. Stock register of vaccine and logistic were available only in 15 (83.33%) centers as per norm, out of this only 12 (66.66%) CCPs these register were maintained and updated at the time of visit. In a similar study done by Naik AK et al in Surat reported 95 % of health centers had stock register out of which only 85% were maintained and updated properly.¹¹

CONCLUSION

Quality of vaccination programme depends upon existing and sustainable standard Cold chain and logistics management at Peripheral Health Institutions (i.e. PHCs). Our study reveals that Cold Chain and Logistic Management component were not up to the mark in study area. Supervision of such system was also compromised. The issues that we observed in the form of various component of Cold Chain system were ranges from infrastructure, availability of vaccine and Cold Chain Handler's awareness and practice to tackle issues found during study period. The most remarkable and crucial observation was freeze vaccines and stock out of few EPI vaccine. These observations may adversely affect the impact of immunization programme and can ignite the situation of epidemic of Vaccine preventable diseases.

Recommendations

Author strongly objects the freeze vaccine and stock out situation in the peripheral health facility and recommends strong monitoring and close supervision of vaccine and logistics management in studied CCPs. To avoid freeze and stock out situation of vaccine, supply of EPI vaccine should be in top priority in support of effective vaccine and cold chain and logistics management system. We

also recommend continuous training and supportive supervision of Cold Chain Handlers to address remarkable findings of this study. Periodic onsite supervision by Medical officer in-charge/District Immunization Officer about correct cold chain practices would be helpful to ensure quality of immunization serves in the study area.

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