

Evaluation of Cold Chain System at PHCs (Primary Health Centers) of Rajkot District, Gujarat

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Abstract:

Introduction: Immunization of all children with potent vaccines is as important as to achieve desired immunization coverage in the fight against vaccine preventable diseases. Cold chain is an important device to maintain the efficacy and potency of the vaccine intact. **Objectives :** (1) To assess the adequacy of logistics required for proper cold chain maintenance. (2) To assess the quality of maintenance of the cold chain equipments. (3) To identify the gaps and help in correcting them. **Method :** A cross sectional study in the areas of Rajkot district was conducted during the period April 2013 to March 2015. Convenient Random Sampling technique was applied. Pretested semi-structured check list used as a study tool. **Results :** 73% of the cold chain handlers found trained for cold chain maintenance. At two sites ILR and DF were not available. Few sites were lacking in thermometer (8.3% DFs), vaccine carrier (5.3%), cold box (5.3%) or ice packs (2.6). At 100% sites vaccines were stored inside ILR and temperature of ILR was in the desired range of two to eight degree centigrade. Updated temperature log books found at 86.1% sites. Proper ice packs arrangement inside the DF in 83.3% cases. Only 85% BCG vials and 93% of measles vials were having time of reconstitution written on the vials. Open vial policy was also followed only at about 75% sites on average. **Conclusion :** There are no issues with infrastructure, equipments or logistics. Quality cold chain maintenance especially in the areas of maintaining temperature record, following open vial policy, writing time of reconstitution on the vial etc have scopes for improvement. All these can be done by quality supervision.

Key words : cold chain, evaluation

Introduction :

India has one of the largest immunization program in the world.^[1] Immunization is one of the most cost-effective strategy in reducing childhood morbidity and mortality.^[2,3] 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.^[1,4]

Cold chain maintenance is a continuous and cohesive process of preserving vaccines to ensure their availability and to maintain potency. Cold chain maintenance is a term defined as the materials, equipments and procedures used to maintain temperatures between +2°C to +8°C while in transit throughout the distribution and storage process for vaccines from the manufacture point up to the beneficiary; whereas cold chain also includes the people i.e. health workers also engaged to maintain

the equipment and temperature at peripheral levels.^[5,6] A cold chain break denotes a disruption in "cold chain maintenance", which could contribute to significant clinical outcomes, such as adverse reactions and/or missed opportunities to vaccinate.^[5]

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. Vaccines when not stored or transported at an appropriate temperature can lose their potency and not effective if administered to the beneficiary.^[3]

Objectives :

- To assess the adequacy of logistics required for proper cold chain maintenance.
- To assess the quality of maintenance of the cold chain equipments.

- To identify the gaps and help in correcting them.

Method:

Study Design : The study was designed as cross sectional study

Sampling Technique : Convenient Random Sampling was applied to select a desired sample. All the PHCs were divided in two broad groups: High Priority Talukas (HPTs) and Non-High Priority Talukas (NHPTs). Equal number of samples was selected from both the groups.

Sample Size : All the visits made in the time frame of April 2013 to March 2015 were included in the study. Total 38 PHC visits are included in the study. Among which 19 visits were of HPTs and 19 visits from NHPTs.

Study Period : Two years, from April 2013 to March 2015.

As per the guideline from the Health & Family Welfare Department, Gujarat State Regional Monitoring Team (RMT) members, PDU Medical College, Rajkot make regular visits of allotted areas. There are 36 Primary Health Centres (PHCs) in Rajkot district. As per the guideline from the state, Talukas are divided in High Priority Talukas (HPT) and Priority Talukas (PT) and Normal Priority Talukas (NPT).^[19] As per the state policy it was instructed to make visits of HPTs to others in the proportion of 1:3. The standard semi-structured pretested questioner was used as a tool of study. Medical Officers and District Health Officers were informed prior the

visits. Important information regarding, human resources involved in cold chain handling, equipments necessary for cold chain maintenance and quality of cold chain maintenance at both PHC (Facility Site level) and VHND Site (Village Health and Nutrition Day Sites). VHND is famously known as Mamata Divas in Gujarat, where all the services related to Maternal and child health services are provided. Basic services like, immunization services, ANC check up, nutritional supplements, health check up and treatment of children, PNC check up and advises, adolescent girl immunization and health education, etc are provided at least once a month at almost all villages on a fixed day, fixed site with the help of skilled team lead by Female Health Worker (FHW).

Handbook on immunization guidelines by the government of India recommended that each equipment should be connected to voltage stabilizer with permanently secure plug and socket.^[8] The GOI protocol also recommended that ice-lined refrigerators and deep freezers be supported on wooden blocks and be located at least 10 centimeters away from walls.^[9] As per Guideline given in Handbook on immunization by the government of India it is recommended that t-series vaccines (i.e, Hepatitis B, DPT, Pentavalent and TT vaccines) must not be freeze during its storage, because they are cold freeze sensitive vaccines and lose its effectiveness if freeze.^[8]

The data entry and analysis was done using Microsoft office excels.

Results:

Table 1: Distribution of various PHCs as per the available trained human resources for Routine Immunization

Sr. No.	Characteristics	Frequency (f)	Percentage (%)
1	MO training status (N=35)*		
	Trained for Routine Immunization	30	75.7
	Not trained for Routine Immunization	05	24.3
	Total	35	100.0
2	Cold chain handler training status (N=38)		
	Trained for cold chain maintenance	28	73.0
	Not trained for cold chain maintenance	10	27.0
	Total	38	100.0

*At three PHCs post of Medical Officers were vacant.

It was found in present study that 3 out of 38 visited PHCs had vacant posts for Medical Officers. In the rest of the centers having filled posts of Medical Officers around three fourth (75.7%) were found trained for the routine immunization. [Table 1]

Similar kind of picture was found for the cold chain handlers, the pharmacist most of the times or may be other identified staff in case of post vacant. 73% of the cold chain handlers were found trained for cold chain maintenance. [Table 1]

Table 2: Availability of necessary cold chain equipments at PHCs

Sr. No.	Equipments (N=38)	Frequency (f)	Percentage (%)
1	Functional ILR	36	94.7
2	Functional DF	36	94.7
3	Thermometers for ILR*	36	100.0
4	Thermometers for DF*	33	91.7
5	Stabilizer for ILR*	35	97.2
6	Stabilizer for DF*	35	97.2
7	Wooden or other stand for ILR*	36	100.0
8	Wooden or other stand for DF*	36	100.0
9	Cold boxes	36	94.7
10	Adequate number of vaccine carriers	36	94.7
11	Ice packs in adequate amount	37	97.4

* Percentage is calculated using N=36

The present study observed that there is almost no issue of equipments. At two sites Ice Lined Refrigerator (ILR) and Deep Freezer (DF) were not available. The reason was that they were newly built PHCs and the vaccine supply was from the nearby

PHC. [Table 2] The present study findings say that few sites were lacking in thermometer (8.3% DFs), vaccine carrier (5.3%), cold box (5.3%) or ice packs (2.6), but that all are in single digit of percentage. [Table 2]

Table 3: Maintenance of cold chain equipments and related records at PHCs

Sr. No.	Maintenance of cold chain (N=36)	Frequency (f)	Percentage (%)
1	Storage of all vaccines inside ILR	36	100.0
2	Temperature inside ILR between 2-8	36	100.0
3	Temperature log book updated	31	86.1
4	Frozen DPT/DT/TT/Hep B	0	0.0
5	Expired vaccines	1	2.7
6	Other medicines stored inside ILR	0	0.0
7	Icepacks correctly arranged	30	83.3

Our study shown that ice packs arrangement inside the DF was proper in 83.3% cases where still scopes of improvement and efforts. [Table 3]

vaccines were stored inside ILR and temperature of ILR was in the desired range of two to eight degree centigrade. [Table 3] In our study nowhere we found frozen t-series vaccine (i.e, Hepatitis B, DPT,

In our study we found that at 100% sites

Pentavalent and TT vaccines) or other medicines found inside ILR. At one site expired vaccine vial was

found inside the ILR. Updated temperature log books found at 86.1% sites. [Table 3]

Table 4 : Quality of cold chain maintenance at VHND sites

Sr. No.	Quality of cold chain (N=38)	Frequency (f)	Percentage (%)
1	Vaccines/diluents placed in zipper bag	37	97.4
2	Vaccines/diluents placed in vaccine carrier having 4 conditioned ice-packs	38	100.0
3	Vaccine without label/unreadable	00	0.0
4	VVM stage III/IV	01	2.7
5	Expired vaccine	00	0.0
6	Frozen t-series vaccine	01	2.7
7	Time of reconstitution written on reconstituted BCG (n=20)	17	85.0
8	Time of reconstitution written on reconstituted Measles (n=29)	27	93.1
9	Time and date of opening written on the vial of Pentavalent (n=34)	24	70.6
10	Time and date of opening written on the vial of DPT (n=31)	24	77.4
11	Time and date of opening written on the vial of TT (n=34)	25	73.5

Vaccine Vial Monitor (VVM) is a heat sensitive device. Its heat sensitive portion changes its color from white to dark black irreversibly in phase wise manner once exposed to heat or sunlight. There are four stages of VVM. It guides the field workers if can be used or should be discarded. As per the guideline vaccine can be used in VVM stage I and II and should be discarded if found with VVM stage III or IV.^[8] Our study shown that at one site vaccine vial with Vaccine Vial Monitor (VVM) III/IV found in use, while at one site frozen DPT vaccine was found in use. [Table 4] Only 85% BCG vials and 93% of measles vials were having time of reconstitution written on the vials which must be 100% for ideal practice to avoid major Adverse Effects Following Immunization (AEFI). Since 2013 open vial policy is implemented in the state of Gujarat and it was revised in year 2015. According to the guideline of open vial policy, OPV, Hepatitis B, DPT, Pentavalent, TT and IPV vaccines can be used up to four weeks from the day of opening if proper cold chain maintenance is assured and VVM

is in the usable state.^[20] For assuring the same date and time of opening vials are to be written on the vial. Open vial policy was also followed only at about 75% sites on average. Unlabeled vials for time of opening under open vial policy can lose its potency if not used and stored as per the guidelines. [Table 4]

Discussion :

It was found in present study that the 73% cold chain handlers, the pharmacist most of the times or may be other identified staff in case of post vacant, were found trained for cold chain maintenance. Mallik S. et al^[7] also observed that one designated worker as cold chain handler was in 95% of organizations.

The present study observed that there is almost no issue of equipments. At two sites ILR and DF were not available. The reason was that they were newly built PHCs and the vaccine supply was from the nearby PHC. Lalitha Krishnapuram et al^[10] reported that 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^[11] (98.6%); and Goel et al^[12] (92.5%). However the finding of study by Doeki et al^[13] (78%) was less compared to other studies.

The present study findings say that few sites were lacking in thermometer (8.3% DFs), vaccine carrier (5.3%), cold box (5.3%) or ice packs (2.6%), but that all are in single digit of percentage. The similar findings are noted by study of Lalitha Krishnappa et al who observed that only 31 ILR (97.14%) had functional thermometer of which 21 were stem thermometer and 10 were dial thermometer.^[10]

It was recommended that ice-lined refrigerators, deep freezers and refrigerators would maintain a temperature of 2° to 8° C and a temperature maintenance chart.^[8,9] In our study we found that at 100% sites vaccines were stored inside ILR and temperature of ILR was in the desired range of two to eight degree centigrade. Mallik S. et al observed that 55% of the organizations maintained temperature chart, 60% recorded temperature twice and 80% maintained temperature in optimal range.^[7] A study in Canada had shown that the general and pediatric practice offices had maintained temperature chart, but only one third had temperature within limits.^[14] Lalitha Krishnappa et al observed that in 8 (23.5%) ILRs temperature was not in the recommend range.^[10] These results concurred with findings of Samanth et al who found that 75% of ILR in primary health centers in rural area^[15] and Mallik et al in 80% of centers in metro city maintained temperature in optimal range.^[7] In a study done by Harsha Kumar et. al correct temperature was not maintained in 31.25% of the studied health centres.^[16]

In our study nowhere we found frozen t-series vaccine or other medicines found inside ILR. At one site expired vaccine vial was found inside the ILR. Updated temperature log books found at 86.1% sites. Lalitha Krishnappa et al reported that in 91% maintained temperature monitoring chart adequately.^[10] Alike findings are noted in other studies, 94.2% (Rao et al), 55%(Mallik et al) and 65%

(Samanth et al) of the centers have adequately maintained the temperature monitoring chart.^[11,7,15]

As per guidelines, ice packs need to be stacked in criss-cross manner in deep freezer.^[17] This allow even distribution of temperature and proper preparation of ice-packs. Our study shown that ice packs arrangement inside the DF was proper in 83.3% cases where still scopes of improvement and efforts. Lalitha Krishnappa et al reported that criss-cross arrangement of ice packs was seen only in 23%.^[10] Similar observations made in one-third of the health centres of Surat city.^[18]

Our study shown that at one site vaccine vial with VVM III/IV found in use, while at one site frozen DPT vaccine was found in use. Lalitha Krishnappa et al reported in the study that about 97.1% of the centers, the vaccines were in usable condition i.e. in stage-1 and stage-2.^[10] Only 85% BCG vials ad 93% of measles vials were having time of reconstitution written on the vials which must be 100% for ideal practice to avoid major AEFIs. Open vial policy was also followed only at about 75% sites on average. Unlabeled vials for time of opening under open vial policy can lose its potency if not used and stored as per the guidelines.

Conclusion and Recommendations :

Infrastructure, equipments and logistics are no more an issue. But still quality maintenance has scopes of improvement. Frozen t-series vaccine and vaccine with VVM stage III/IV itself suggests that temperature maintenance in the desired range is not maintained all the time. The same thing is indirectly reflected with gap in temperature log book maintenance. Still more serious issues found are not writing date and time of opening of vial which may again raise doubt of vaccine efficacy if open vial policy is not well followed. In case of vaccine vials like BCG and measles not writing time of reconstitution may lead to major AEFI and can lead to adverse impact on the program. The identified issues were corrected on the spot with the help of concerned staff when possible, else communicated to the concerned person right from grass root level (Health Supervisor) to State authorities for needful actions. The findings

were shared with Taluka officials by telephonic talk, and by e-mail reports with MOs, THOs, CDHO, RCHO, State Immunization Officer and Additional Director (FW) for feedback and corrections if any required. The major gap identified was the quality of supervision. All the issues found can be well handled with tactful supportive supervision and vigilant monitoring.

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References:

- Govt. of India. Handbook for vaccine and cold chain handlers. Ministry of Health & Family Welfare, New Delhi; 2010. Available from [www.unicef.org/india/Cold_chain_book_Final_\(Corrected_19-04-10\).pdf](http://www.unicef.org/india/Cold_chain_book_Final_(Corrected_19-04-10).pdf). Accessed on 2013 March 1st
- National Rural Health Mission & United Nations Children's fund. National cold chain assessment India, July 2008. New Delhi, India: UNICEF & NRHM; 2008. Available from: http://www.unicef.org/india/National_Cold_Chain_Assessment_India_July_2008.pdf. Accessed on 2013 March 17th
- LalithaKrishnappa, Arvind B Anniappan, Narayan H Voderhobli. Evaluation of cold chain practices in urban health centres of a metro city in India. National Journal of Community Medicine Volume 5; Issue 3: July-Sept 2014
- Guidelines on how to maintain vaccine cold chain. Available at: https://www.moh-ela.gov.sg/ela/content/Vaccine_Cold_Chain.pdf2005. Accessed on April 10 2013
- Seto J, Marra F. Cold chain management of vaccines. CPD; February 2005
- Sudarshan MK, Sundar M, Girish N, Patel NG. An evaluation of cold chain system for vaccines in Bangalore. Indian J Pediatr 1994; 61:173-8. [PubMed]
- 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 African Health Sciences Vol 11 No 1 March 2011
- Govt of India. Immunization handbook for health workers, Ministry of Health & Family Welfare, New Delhi; 2006
- WHO-India. Operations guide for program managers, 2002. [cited 2009 Sep 28]. Available from: URL:http://www.whoindia.org/LinkFiles/Hepatitis_B_Operations_Guide.pdf.
- Lalitha K, Arvind B, Narayana H V, Shantha K, Sudarshana Y, Pruthvish S. et al Evaluation Of Cold Chain Practices In Urban Health Centers Of A Metro City In India, National Journal of Community Medicine Volume 5 Issue 3 July - Sept 2014
- Rao S, Naftar S and Baliga S and Unnikrishnana B. Evaluation, st. Awareness, Practice and Management of Cold Chain at the Primary Health Care Centers in Coastal South India. Journal of Nepal Paediatr. Soc, 2012; 32 (2):19-22
- Goel NK, Swami HM, Bhatia SP. Evaluation of cold chain system Chandigarh during PPI campaign 2001-2002. Indian J Public Health. 2004;48:200-204
- Deoki Nandan, Hamid Jafari, UtsukDatta, Sunil Bahl, Renuparuthi, Bhattacharya M et al. Performance Assessment of Health Workers Training in Routine Immunization in India (WHO and NIHFw collaborative study). India: December 2009.
- L. Yuan, S. Daniels, M. Naus, and B. Brcic. Vaccine storage and handling: Knowledge and practice in primary care physicians' offices. Can Fam Physician 1995 July; 41: 1169-1176.
- Samant Yogindra, Hemant Lanjewar, David Parker, Lester Block, Gajendra S. Tomar, Ben Stein. Public Health Rep. 2007 Jan-Feb; 122(1): 112-12.
- Harsha Kumar HN, Aggarwal A. Cold Chain Maintenance and th Vaccine Administration Practices in hospitals & clinics of Mangalore City -A Health System's Research. Natl J Community Med 2013;4(2): 231-235.
- Government of India. Immunization hand book for Medical Officers. Ministry of Health & Family Welfare, New Delhi; 2008. [Available from <http://nihfw.org/pdf/NCHRCPublications/ImmuniHandbook.pdf>] Accessed on 2013 March 1st.
- Naik Ashish, Rupani Mihir, 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. Available from: <http://ijpm.mui.ac.ir/index.php/ijpm/article/view/916>. Accessed on 2013 July
- Guideline for mapping of Talukas as per priority. Available from: http://gujhealth.gov.in/images/pdf/Inclusive_Health_Care_Shri_Harit_Shukla.ppt. Accessed on 2015 December.
- Letter No. FW/Imm/Pentavalent/2015/146 dated 23/09/2015 from Commissionerate of Health, Medical Services and Medical Education, Gandhinagar.