



Improvement of Quality of Cold Chain System Through Involvement of Health Care Providers

Das Palash	MD, Associate Professor, Paschim Medinipur, West Bengal, India
Haldar Anima	MD, Professor, Paschim Medinipur, West Bengal, India
Sinha Nirmalya	MD, Associate Professor, Paschim Medinipur, West Bengal, India
Baur Baijyanti	MD, Professor, Paschim Medinipur, West Bengal, India
Sahu B	MBBS, Demonstrator, Paschim Medinipur, West Bengal, India
Yasmin Samima	MD, Assistant Professor, Paschim Medinipur, West Bengal, India

ABSTRACT

Improvement of quality of cold chain system through involvement of health care providers

Background: Vaccine carriers, Cold box, Ice-lined refrigerator (ILR), Deep freezer (DF) are the different cold chain equipments to be used in health care delivery system to maintain the quality of vaccines. **Objectives:** To assess the improvement of quality of cold chain system through training of multipurpose health workers. **Materials and Methods:** This was an intervention study. Multistage random sampling technique was adopted to select the session sites. Settings were various selected vaccine storage points (PHCs, BPHCs) and fixed & outreach session sites. Inclusion criteria included all the PHCs and BPHCs with fixed vaccine storage facilities for cold chain assessment and one and single Sub-Centre selected randomly from each PHC for vaccination. Centres wherefrom staff did not attend the training were excluded. Tools for data collection were pre-designed, pre-tested and semi-structured schedule. Ethical clearance was taken from Institutional Ethics Committee, Midnapore Medical College. Epi-Info version 7.0 was used to derive information from the data. **Results:** Vaccine storage points were 42 and vaccination service points were 38. ILRs and DFs placed on wooden blocks were found significantly different after intervention. Ice-packs condition in vaccine-carriers was found improved. Cabinet temperature was found significantly better in post intervention period. Correct placement of icepacks, keeping vaccines in deep freezer were found with significant improvements. Vaccine supply in plastic zipper bag increased in significant amount. **Conclusion:** This study reflects the benefit of intervention. The effects of educational intervention showed marked quality improvement in different components of cold chain system. Reorientation training for health care providers can be organized at regular interval to improve the quality of cold chain system.

KEYWORDS

Grass-root workers, Health education, improvement, quality of cold chain system

Background:

Quality of health care is a multidimensional and multifaceted concept. Quality has been defined as a process of meeting needs and expectations of customers both internally and externally, and a process of continuous incremental improvement.¹ Quality is a concern to everybody. Quality involves trust of people who believe the product or service will be free from defect, no deficiency and significant variation. Users' requirement can be satisfied only through strict, untiring and consistent commitment achieving uniformity in product or service.²

Government of India set Indian Public Health Standards (IPHS) at different levels of health care to ensure the quality.³⁻⁵ Vaccine carrier, Cold box, Ice-lined refrigerator, Deep freezer are the different cold chain equipments to be used in health care delivery system to maintain the quality of vaccines. These are components of cold chain system which is managed by health care providers.

Differences were observed in terms of coverage and quality of services. Special interventions should be undertaken on a priority basis to bridge those gaps so as to achieve the Millennium Development Goals in all population groups.⁶

Cold chain is defined as a process used to maintain optimal conditions, temperature in particular, during the transport, storage, and handling of vaccines, starting at the manufacturer and ending with the administration of the vaccine to the client. The optimum temperature for cold chain in refrigerat-

ed vaccines is between +2°C and +8°C.⁷ Cold-sensitive vaccines experience an immediate loss of potency if vaccines are frozen. Vaccines exposed to temperatures above the recommended temperature range experience some loss of potency with each episode of exposure to temperature above the recommended one. Repetitive exposure to heat episodes results in a cumulative loss of potency that is not reversible.⁷ So cold chain is important and very much required issue in valid vaccination programme. Quality of cold chain system thus improves the quality of vaccine and vaccination

The aim of training is to develop new knowledge, skill, or expertise. Training is more than just learning, since training should have a goal of improved performance at some specified task.⁸ Health care providers who are involved in vaccination activities and management of cold chain are Auxiliary Nurse & Midwives (ANMs) working as Multipurpose Health Workers (MPHWs) at sub-centre level, Health Assistants (HA) in Primary Health Centre (PHC) level and Public Health Nurses (PHNs) at Block-level Primary Health Centre (BPHCs) or Community Health Centre (CHC) or Rural Hospital (RH) level. It is expected that knowledge intervention among multipurpose health workers and other superior staff may be one of the activities to do health practice in better way with quality.

Keeping this view in mind this study was contemplated to assess the improvement of quality of cold chain system at storage points and vaccination session sites through training of multipurpose health workers

Materials and Methods:

This was an **intervention study** in the district of Paschim Midnapore of West Bengal in India. Study was conducted during **July to December 2013**. **Multistage random sampling** technique was adopted to select the session sites. Paschim Midnapore District has both rural and urban areas. District has four subdivisions namely Kharagpur, Midnapore, Jhargram and Ghatal which are composed of rural community development blocks. Each block is subdivided into four sub-blocks (PHC area) and these sub-blocks are again subdivided into six sub-centre (SC) areas of approximately five thousand population. Vaccination services are given from sub-centres and outreach field areas. PHC, BPHC, CHC, RH have one and single sub-centre in the premise of these set ups to provide vaccination service along with other services. And they are serving as vaccine storage points. Three BPHCs / RHs each have been selected from Kharagpur, Midnapore, and Jhargram subdivisions and two BPHCs/RHs have been selected from Ghatal subdivision. Kharagpur and Midnapore Municipalities have been selected as urban area. All the PHCs from the selected BPHCs/RHs and one sub-centre from each PHC and all the immunization clinics of both the selected municipalities were the sample population in rural and urban area respectively. **Settings** were various selected vaccine storage points (PHCs, BPHCs) and fixed & outreach session sites. All of the peripheral level cold chain units in the districts and one-sixth of vaccination session sites from selected health facilities were taken as sites for cold chain activities by the health workers. So **Inclusion criteria** included all the PHCs and BPHCs with fixed vaccine storage facilities for cold chain assessment and one and single Sub-Centre selected randomly from each PHC for vaccination. **Exclusion criteria** included centres wherefrom staff did not attend the training on cold chain system. **Tools** for data collection were predesigned, pretested and semi-structured schedule. Tools were validated by five public health specialists. **Ethical clearance** was taken from Institutional Ethics Committee, Midnapore Medical College, West Bengal. **Variables** were the matters related to storage (freezer placed on wooden blocks, separate functional voltage stabilizer for freezers etc) and related vaccination site activities (placement of ice-pack in vaccine carrier, vaccine and diluents in plastic zipper bag etc);

Procedure:

Collection of data was done by faculty members of community medicine of different medical colleges of West Bengal. Present status or situation has been identified through this data. Intervention was materialised through health education on cold chain system and its management through Health Care Providers working in the vaccine storage level and vaccination level. Continuation of services has been allowed in all the centres and it was allowed for six months. Then re-assessment was done using the same schedule. **Statistical analysis:** MS Excel was utilized to record the data. Epi-Info version 7.0 was used to derive information from the data. Confidence limit was 95% and significance level was at 5% level

Results:

Vaccine storage points were 42 in number and vaccination service points were 38 in number in this study. The principal variables related to vaccine storage points were Ice-Lined Refrigerators (ILRs) or Deep Freezers (DPs) placed on wooden blocks, separate functional voltage stabilizer for each and single refrigerator, functional thermometer placed inside, no frost or < 5 mm frost on inside walls, < 48 hrs taken for repair etc. ILRs and DFs were seen placed on wooden blocks in different numbers during pre and post intervention period and this was found statistically significant.

ILRs and DFs placed on wooden blocks were found low in number in pre-intervention time and it increased after training (Table 1). This change of increase was significantly different ($Z = 2.10, p = 0.03$). Separate functional voltage stabilizer for each and single ILR or DFs was found low and the proportion of stabilizers increased in good size which was significantly different ($Z = 2.01, p = 0.04$). In the similar way, functional thermometer placed inside the ILRs and DFs & time taken for

repair (< 48 hrs) were found significantly high after education intervention ($Z = 2.89, p = 0.003$; $Z = 2.61, p = 0.008$). No frost or < 5 mm frost on inside walls was found in good number both in pre and post intervention time. The difference was not significant.

Temperature monitoring is very crucial for keeping the vaccine potent. Times of temperature check up in a day, power supply to freezers and concurrent random evaluation of check-ups are essential components for this safety job (Table 2). Two times checks with equal time gap in a day were seen from record and it was found significantly higher in post intervention period ($Z = 2.26, p = 0.02$). Similarly record of power failure or cut or defrost was checked and it was found poor (28.6%) in pre intervention period. After education training it increased in a bigger size (78.6%) though less than expected level and this was statistically significant ($Z = 4.59, p = 0.00$). Periodic temperature check-ups by superior staff was still poor after education training (from 50% to 57%) and this increase was found insignificant statistically ($Z = 0.65, p = 0.50$).

Different activities were observed in relation to ILRs (Table 3). Maintenance of cabinet temperature, inside cartoon arrangement, T-series vaccine and diluents placement were noted in both the times of pre and post intervention period. Cabinet temperature was found improved significantly ($Z = 3.17, p \text{ value} = 0.00$) and all other activities were improved but these were not significantly different.

Cabinet temperature check-ups, correct placement of ice-packs, keeping vaccines in deep freezer were noted during pre and post intervention period (Table 4). All these were found with significant improvements ($Z = 3.74, 4.09, 3.50$ and $p \text{ value} = 0.00, 0.00, 0.00$ respectively). Education intervention worked here in all these respects.

Ice-packs were observed in vaccine carriers. Status of conditions of ice-packs such as frozen hard or conditioned or melted fully was the issues of interest (Table 5). Hard frozen ice-packs were less in number both in pre and post intervention period. The difference was found insignificant. Conditioned Ice-packs were seen increased in post intervention period and this increase was not found significant statistically. Fully melted ice-packs were seen among 21 percent of vaccine carriers and it decreased in high quantity. The difference between pre and post intervention period was found significant statistically ($Z = 2.99, p = 0.00$).

Vaccines in vaccine carriers are distributed on the day of vaccination from the storage place. This was found in 100 percent cases in pre and post intervention period. (Table 6). Vaccine carriers with four ice-packs were found increased to 100 percent in post intervention period. This was high in pre intervention period, the difference was not found statistically significant. Vaccines and diluents were seen whether these were supplied in plastic zipper bag. It was found that vaccine supply in plastic zipper bag increased in good amount which was statistically significant ($Z = 2.71, p = 0.01$).

Discussion:

This study was conducted in a rural district of West Bengal in India. Vaccination is an important timely strategy to overcome certain communicable disease problem in India. The efficacy of this vaccination depends upon cold chain system which can provide real sense of security.

Distribution of attributes related to vaccine storage point: ILRs & DFs:

ILRs and DFs were found correctly placed on wooden blocks after intervention in 78.6 percent cases. Similar picture (76.1%) was also found in another study done in Bijapur district of Karnataka.⁹ Separate functional voltage stabilizer was seen from 50.0 percent to 76.9 percent in this study. This is corroborating the findings of Damoh district study (66.6%) of Madhya Pradesh.¹⁰

Functional thermometer placed inside both DFs and ILRs were improved very high from 57.1 percent to 85.7 percent. Pre intervention period findings were poor and even after intervention, this has not reached to cent percent though difference was found significant statistically. Higher values of this study were found similar with previously mentioned Bijapur & Damoh studies^{9,10} and Ahmedabad Municipal Corporation study.¹¹

No frost or < 5 mm frost on inside walls was found in good quantity even before intervention. A palpable increase was seen in post intervention period without any significant difference. In cent percent cases, no frost or < 5 mm frost inside walls of freezer was found in Bijapur study⁹ and this was found in less number (66.6%) in Damoh study.¹⁰ In one study at Jamnagar district, cent percent ILR was found with this picture but DFs were found with no frost or < 5 mm frost inside walls at the rate of 14.4 percent.¹² Intervention in this study did not raise the frost issue in favorable side. This is really a question.

< 48 hrs taken for repair was really poor in both the pre intervention and post intervention period though with significant difference but the cause for this poor attention or performance should be found out.

Monitoring of temperature, power continuity and its verification

Significant improvement was seen in respect of temperature check up (twice daily) of both types of freezers, record of power failure/cut/defrost (from 28.6% to 78.65) etc. This was found in low level in around 38 percent cases in Ahmedabad study.¹¹ Other study found temperature check up in 33.3 percent cases and power failure or cut in 66.6 percent cases.¹⁰ Jamnagar study revealed temperature check up in 100 percent cases but power failure record was seen in 50 percent.¹² All the studies revealed the gloomy picture of temperature monitoring and continuity of electrical power supply. Periodic check up by superior staff for monitoring temperature was found without any increase even after intervention in this study. This was good in Ahmedabad study.¹¹ This was cent percent in Damoh district study.¹⁰ Two-third portion of set ups was found with signature of medical officers in Jamnagar study.¹²

Distribution of activities in Ice Lined Refrigerators

Cabinet temperature of the Ice Lined Refrigerators was seen improved significantly after intervention, but in pre intervention period, recommended temperature was found in 78.6 percent refrigerators which cannot keep the vaccine potent. Similar picture (66.6%, 74.2%) was found in some other studies.^{10,13} Recommended temperature was seen in many more studies in good proportion (93.5%,⁹ 96.0%,¹¹ 100.0%¹²). This variation should be minimized and it should be maintained in cent percent cases to keep the vaccine effective.

Vaccines were found correctly arranged inside cartoon in fair number (71.4%) before health education training and it increased to good number (85.7%) after training without significant difference. This increase should reach cent percent. In this correct placement of vaccines in ILRs, variations were found in high amount (58.7%,⁹ 66.6%,¹⁰ 35.0%,¹³ 96.0%¹⁴).

No T-series vaccine placed at bottom in this study were good in number. Similar findings 84.8%,⁹ 66.6%¹⁰ and 90.0%¹⁴) were seen in some other studies. Diluents placed 24 hrs before distribution were found fair in number in pre intervention period and increased in very good number after intervention. Other studies found the picture in very good number (95.6%,⁹ 100.0%,¹⁰ and 98.0%¹⁴). In this study the training has raised the findings without significant difference. Constant motivation or supervision might help the situation.

Frequency distribution of activities in Deep Freezers

Cabinet temperature (- 15 to - 25) in Deep Freezers were found increased (100.0%) significantly though it was poor in pre intervention period (71.1%). Low picture was found in

one Metro City study.¹³ Other studies found the recommended temperature from moderate to good quantity with a definite variation (91.3%,⁹ 66.6%,¹⁰ 79.3%¹¹).

Correct placement of ice-pack in Deep Freezers was poor (42.9%) in pre intervention period but very well (85.7%) after intervention in this study. Other studies found the placement of ice-packs in moderate quantity (73.9%,⁹ 66.6%,¹⁰ 62.0%¹⁴).

No vaccine including reconstituted one kept in Deep Freezer was not the finding in this study in pre intervention period which was very poor (50.0%) but after training it raised to the level of 85.7 percent. This after-training result also was poor to other study findings (100.0%).^{9,10}

Distribution of ice-packs condition in vaccine-carriers

Hard frozen, conditioned and fully melted ice-packs were noted in this study. Hard frozen and conditioned ice-packs were found in good quantity in pre intervention period and both the findings increased after intervention. Fully melted ice-packs were seen before intervention and it was not found after intervention. This was really a good achievement and the difference was statistically significant. In one study the knowledge of the cold chain handlers were tested and they found that 54 percent workers were seen with right knowledge of ice-pack conditions.¹³ Other study observed that 80 percent of ice-packs were seen conditioned.¹⁴ This variation of results on ice-pack condition might be minimized by repeat training, monitoring.

Distribution of some attributes related to cold chain

Vaccine carriers were found distributed on the same date for vaccination in both the pre intervention and the post intervention period. This was a good practice seen in all centres in this study. Vaccine carriers with 4 ice-packs were found in most of the centres of vaccination. This increased to cent percent after intervention. Vaccine distribution and ice-packs number were not studied much in relation to cold chain. This study finding proved that these were taken care of by most of the workers. Vaccine and diluents in plastic zipper bag were not found in pre intervention time but it increased in significant number after intervention. Other study got the similar results.¹⁴

Conclusion:

The effects of educational intervention showed marked quality improvement in different components of cold chain status.

Recommendation:

Reorientation training for health care providers can be organized at regular interval to improve the quality of cold chain system.

Acknowledgement:

Director, NRHM, Govt. of West Bengal; Principal, Midnapore Medical College, Paschim Midnapore; Chief Medical Officer of Health and his associates, Paschim Midnapore District; BMOHs and PHNs of selected BPHCs/RHs, Paschim Midnapore District.

Table 1: Distribution of attributes related to vaccine storage point: ILRs & DFs (n = 42)

ILRs and DFs	Pre-Intervention No. (%)	Post-Intervention No. (%)	Z, p value
Placed on wooden blocks	24 (57.1)	33 (78.6)	2.10 0.03
Separate functional voltage stabilizer	21 (50.0)	30 (76.9)	2.01 0.04
Functional thermometer placed inside	24 (57.1)	36 (85.7)	2.89 0.003
No frost or < 5 mm frost on inside walls	33 (78.6)	36 (85.7)	0.85 0.39
< 48 hrs taken for repair	15 (35.7)	27 (64.3)	2.61 0.008

Table 2: Monitoring of temperature, power continuity and its verification (n = 42)

Attributes	Pre-Intervention No (%)	Post-Intervention No (%)	Z, p value
Twice daily	27 (64.3)	36 (85.7)	2.26 0.02
Record of power failure/cut/defrost	12 (28.6)	33 (78.6)	4.59 0.00
Periodic temperature check up by superior staff	21 (50)	24 (57.1)	0.65 0.50

Table 3: Distribution of activities in Ice Lined Refrigerators (n = 42)

Attributes	Pre-Intervention No (%)	Post-Intervention No (%)	Z, p value
Cabinet temperature (2 to 8)	33 (78.6)	42 (100.0)	3.17 0.00
Correctly arranged inside cartoon	30 (71.4)	36 (85.7)	1.59 0.10
No T-series vaccine placed at bottom	36 (85.7)	39 (92.9)	1.05 0.29
Diluents placed 24 hrs before distribution	33 (78.6)	39 (92.9)	1.87 0.06

Table 4: Frequency distribution of activities in Deep Freezers (n = 42)

Attributes	Pre-Intervention No (%)	Post-Intervention No (%)	Z, p value
Cabinet temperature (- 15 to - 25)	30 (71.4)	42 (100.0)	3.74 0.00
Correct placement of ice-pack	18 (42.9)	36 (85.7)	4.09 0.00
No vaccine including reconstituted one kept in Deep Freezer	21 (50)	36 (85.7)	3.50 0.00

Table 5: Distribution of ice-packs condition in vaccine-carriers (n = 38)

Conditions of ice-packs	Pre-Intervention No (%)	Post-Intervention No (38)	Z, p value
Hard frozen	5 (13.2)	10 (26.3)	1.44 0.14
Conditioned	25 (65.8)	28 (73.7)	0.74 0.45
Fully melted	8 (21.0)	0 (0.0)	2.99 0.00

Table 6: Distribution of some attributes related to cold chain (n = 38)

Attributes	Pre-Intervention No (%)	Post-Intervention No (%)	Z, p value
Vaccine carrier distributed on same date	38 (100.0)	38 (100.0)	Value not calculated
Vaccine carrier with 4 ice-packs	35 (92.1)	38 (100.0)	1.77 0.08
Vaccine and diluents in plastic zipper bag	29 (76.3)	37 (97.4)	2.71 0.006

References:

1. Donabedian A. The quality of care how can be assessed. Special Communication. JAMA 1988; 260:1743-6.
2. <http://www.businessdictionary.com/definition/quality.html#ixzz3kD15xva0> (accessed on 10.12.2015)
3. Indian Public Health Standards (IPHS). Guidelines for Primary Health Centres Revised 2012. Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India. Page 3-18
4. Indian Public Health Standards (IPHS). Guidelines for Community Health Centres Revised 2012. Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India. Page 3-19
5. Gupta M, Thakur JS, Kumar R. Reproductive and Child health inequalities in Chandigarh Union Territory of India. J Urban Health.2008; 85:291-9.
6. Public Health Agency of Canada. Home > Immunization & Vaccines > National Vaccine Storage and Handling Guidelines for Immunization Providers (2007) > Section 1 Cold Chain (available at www.publichealth.gc.ca & accessed on 13.08.2015)
7. Patrick Jhon. Training; Research and practice. Academic Press, London, 1992.
8. Biradar SM, Biradar MK. Evaluation of vaccine storage practices in primary health centres of bijapur district of Karnataka. Int J Pharm Bio Sci 2013 Oct; 4(4): (B) 1290 – 1293
9. Gupta A, Gupta R. Study of Cold Chain Practices at Community Health Centers of Damoh District of Madhya Pradesh. Ntl J of Community Med 2015; 6(4):528-532
10. Govani KJ, Sheth JK. Evaluation of Temperature Monitoring System of Cold Chain at all Urban Health Centres (UHCs) of Ahmedabad Municipal Corporation (AMC) area. Healthline January - June 2015; 6(1):41-5
11. Sanghavi M M. Assessment of routine immunization program at primary health centre level in Jamnagar district. National Journal of Medical Research Oct – Dec 2013; 3(4):319-23
12. Lalitha 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):288-92.
13. Sharma DK, Varun A, Patel R, Singh US. Process Evaluation of Immunization Component in Mamta Diwas and Support Services in Kheda District, Gujarat. Natl J Community Med 2013; 4(1): 81-5.
14. Biradar SM, Biradar MK. Session sites monitoring of routine immunization program in Bijapur district. Int. J. Life Sc. Bt & Pharm. Res. 2013;2(4):232-6