Original Research Article

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Assessment on cold chain management system in selected blocks of Purulia district, West Bengal, India

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ABSTRACT

Background: The study was done to assess the status of cold chain point, vaccine storage practice and practice of health workers about immunization activities at cold chain points. The aim was to evaluate the cold chain system in relation to infrastructure, manpower and maintenance of equipment in selected blocks of Purulia district.

Methods: It was a cross sectional descriptive study, done at randomly selected sites where vaccines were stored and outreach sessions where immunization services were provided. Five cold chain points were included in the study. Fully structured standardized checklists and questionnaire had been used to collect the data.

Results: Only 40% cold chain point (CCP) reported breakdown of cold chain equipment (CCE) in last one year. Ice lined refrigerator (ILR) and deep freezer (DF) were properly placed in 75% of the CCP. All the CCP have displayed contingency plans and latest standard job aids. Vaccines and ice packs were correctly placed. ILR and DF were connected to functional voltage stabilizer. A functional thermometer was placed inside every ILR and DF and twice daily recording of temperature was found in all the CCPs. Record of vaccine wastage was found only in 40% CCPs. CCPs have adequate space for conditioning. No frozen vaccine and vaccine vial beyond expiry date were found in any of the CCPs. All CC handlers had satisfactory knowledge about cold chain management.

Conclusions: This study was an effort to assess the status of cold chain points in Purulia district, West Bengal. Overall result was satisfactory, could have been maintained and further improve in future by good supportive supervision practice as a key measure in improvement of cold chain system.

Keywords: Cold chain point, Cold chain handler, Cold chain equipment, Knowledge

INTRODUCTION

As a public health intervention, vaccines have been instrumental in bringing about a reduction of morbidity and mortality due to vaccine preventable diseases globally. Vaccines in routine immunization (RI) are one of the most cost-effective health investments. Over the years various strategies to make vaccines universally available, including most hard-to-reach and vulnerable populations have saved countless lives. To ensure vaccine safety and effective cold chain management, the National cold chain management information system (NCCMIS)

was established to track the functioning of cold chain equipment across the country. A National effective vaccine management (EVM) assessment was also conducted to identify issues and provide solutions to strengthen cold chain and vaccine management. Vaccines are immuno-biological substances designed to produce specific protection against a given disease. Some vaccines are sensitive to freezing, some to heat and others to light. Vaccine potency, its ability to adequately protect the vaccinated person can diminish when exposed to inappropriate temperatures. Once lost, vaccines potency cannot be regained. Hence for effective implementation of the Universal immunization programme factors like

cold chain and vaccine management needs greater focus, attention, knowledge and skills of the cold chain handler (CCH) and proper implementation of immunization sessions becomes important for the success of the UIP.^{3,4} Cold chain is a system of storing and transporting vaccine at the recommended temperature range from the point of manufacture to point of use.1 Reverse cold chain is a system of storage and transportation of vaccine from the end user of vaccine to the testing laboratory (for potency or contamination test). In order to provide potent and effective vaccine to the beneficiaries a vast cold chain infrastructure is required. India spends about 20,000 million rupees every year on immunization. Ministry of health and family welfare, Government of India publishes vaccine and cold chain handlers (VCCH) handbook to enable CCHs efficiently manages the vaccine and cold chain system by equipping them with the required technical and practical guidance. 1 CCH is the most crucial person at a CCP as his/her correct knowledge and skills regarding cold chain practices, vaccine management and handling are immensely vital for the success of Universal immunization programme. Considering the importance of vaccine management and logistics, hence the present study was carried out with the objectives to evaluate cold chain system in relation to infrastructure, manpower and maintenance of equipments in selected blocks of Purulia district. The knowledge of CCHs regarding cold chain management was also assessed. As despite the importance of cold chain very few published literatures are available on cold chain system in Purulia district of West Bengal. This study aimed to fulfil this gap.

METHODS

Study design

The study design was a cross sectional study.

Study setting

It was conducted at the selected blocks of Purulia district of West Bengal in 5 cold chain points.

Inclusion criteria

Training status and knowledge of CCH, cold chain room, availability of alternate electric supply, availability of vaccines and open vial policy were the inclusion criteria.

Sampling procedure

Multi stage sampling was done. The district was served by 1 district hospital, 1 subdivisional hospital, 20 block primary health centers, 41 cold chain points and 485 functioning subcenters. Out of four subdivision one subdivision, Raghunathpur subdivision was selected randomly of which cold chain point of Raghunathpur subdivisional hospital was selected. Out of six blocks of Raghunathpur subdivision two blocks Neturia block and Kashipur block were randomly selected with two cold

chain points of each block, Harmadih CCP and Raibandh CCP of Neturia block and Kashipur CCP and Talajuri CCP of Kashipur block. So total 4 CCPs from the 2 selected blocks and 1 CCP in Raghunathpur subdivision were selected for the study.

Study tools

Information were collected on pre-designed and pre tested standard supportive supervision checklist and questionnaire for cold chain points.

Data collection procedure

After taking permission from district health authorities the 5 CCPs were visited and check lists were used as study tools for data collection and predesigned and pretested questionnaire was used for assessment of knowledge of the CCHs.

Statistical tool

Data was collected and compiled using MS excel and represented in percentage and proportions.

Study period

The study duration was 6 months (March to August 2021).

RESULTS

In present study it was found that all the health facilities have updated microplan and trained CCH but only 60% of health facilities had trained medical officer, with dedicated room for cold chain. 4 health centres had dedicated space for dry storage, cold box and vaccine carrier were properly stored in the store in all the CCP. Dedicated table for conditioning of icepacks were present in 4 of the health facility. Power back up was available in all the health centres (Table 1). It was observed that in 3 health centers (75%) the ILR and DF were properly placed on wooden stand at the distance of 10 cm from the wall and adjacent equipment. A functional thermometer was placed within a basket inside every ILRs and DFs. ILRs and DFs were connected to separate functional voltage stabilizer in 4 of the health centres. Recording of the temperature in the temperature log book was done twice daily including on sundays and holidays and periodic checking of the log book by facility incharge was done in all the health centres. It was found that in all health centres the cabinet temperature of ILR and DFs was maintained within normal range. Vaccine vials were found accordingly placed and diluents were stored in ILRs. Ice packs were stored in DFs in criss-cross pattern (Table 2).

Only 2 (60%) of the CCPs reported breakdown of CCE in the last 1 year and in all the health facility CCHs knows whom to contact for repairing the CCE. CCT (cold chain technologies) visits were done regularly for planned

preventive maintenance (PPM) in all the health facilities (HF) and where reporting is done CCT visits was done on that day or next and repair done within a week (Table 2). The contingency plan and the job aids were displayed in all the health facilities. The physical stock, standard stock

register and eVIN app were maintained and were updated in all the health facilities. 4 of the health facility have documented alternate vaccine delivery (AVD) plan for session site. Records of vaccine wastage was found only in 40% CCPs (Table 3).

Table 1: Status of equipment maintenance.

Parameters	Yes (N=5)	%
Was there any breakdown of CCE reported from the CCP in the last 1 year?	2	40
Is there an AMC/CMC for repair and maintenance of cold chain equipment?	5	100
If yes, does the VCCH knows whom to contact for CCE under AMC/CMC	5	100
Did the CCT or AMC/CMC service provider visit for PPM in the last 4 months?	5	100
Does the VCCH carry out the daily and weekly PPM as per the checklist?	5	100
All the ILR/DF are placed as per specified guidelines	3	60
Are the cold boxes stored properly in the store?	5	100
Are the vaccine carriers stored properly in the store?	5	100
Are cold box and vaccine carrier cleaned with luke warm water and detergent?	5	100
Are the ice packs correctly placed for freezing in the DF?	5	100
Is the vaccine store building suitable for storing equipment and vaccines?	4	80
Are contingency plans for vaccine storage displayed appropriately?	5	100
Is there planned preventive maintenance checklist for equipment and documentation?	5	100
Are the latest standard job aids displayed in the centre?	5	100

Table 2: Status of temperature monitoring.

Parameters	Yes (N=5)	%
Are there dedicated functional thermometers for each functional CCE?	5	100
Are there dedicated standard temperature log books for each installed CCE?	5	100
Are the twice daily recordings (Holidays) complete and up to date for the last 3 months?	5	100
Is there documentation of monthly review of temperature records?	5	100
Can the VCCH correctly demonstrate temperature reading from the thermometer?	5	100

Table 3: Status of vaccine management.

Parameters	Yes (N=5)	%
Does the CCP have standard vaccine and logistics stock/issue registers?	5	100
Are the registers completely filled and up to date?	5	100
Is there documented evidence of physical stock verification of vaccine and logistics in the last 3 months?	5	100
Record of MR/BCG vaccine and diluents in physical stock, stock register and eVIN app are up to date?	5	100
Does the CCP have documented minimum & maximum stock levels for all antigens?	5	100
Are the vaccines correctly stored in the ILR	5	100
Are the vaccines kept in the basket in the ILR?	5	100
Are the diluents kept in the cold chain at least 24 hours before issuing to the session sites?	5	100
Does the CCE contain only UIP vaccines and diluents?	5	100
Is there any open vaccine vial stored in the ILR without date and time mentioned on it?	0	0
Is there any frozen vaccine in the ILR?	0	0
Is there any vaccine vial beyond expiry date in the ILR?	0	0
Are record of vaccine wastage being reviewed and kept in a safe place for last three years?	2	40
Is there adequate space available for conditioning of icepacks?	4	80
Is there any vaccine kept in the deep freezer?	0	0
Does the CCP have documented AVD plan for all the session sites?	4	80
Are all AVD volunteer aware of the precautions and safety measures to prevent COVID infection?	5	100
Is the vaccine store and its premises including the store keepers office clean?	5	100

Table 4: Knowledge of vaccine management by CCHs.

Parameters	Yes (n=5)	%
Can the VCCH correctly demonstrate ice pack conditioning?	5	100
Can the VCCH correctly demonstrate knowledge of shake test?	5	100
Does the VCCH have Knowledge about VVM	5	100
Does the VCCH have knowledge about the time of use of reconstituted vaccine	5	100
Does the VCCH have knowledge about the timing of placement of diluents inside ILRs	5	100
Does the VCCH have knowledge about which vaccines require diluents	5	100
Does the VCCH have knowledge about the cabinet temperature range of ILRs and DFs	5	100
Can the VCCH identify the freeze sensitive vaccines and temperature sensitive vaccines.	5	100
Does the VCCH have knowledge about open vial policy	5	100

It was noticed that in all health centres, all vaccine vials were found within expiry dates, with usable (vaccine vial monitor) VVM. No vaccine was found in frozen condition, open vaccine vial were stored in separate box, date and time of opening was written on the vial. All open vaccine vials were of less than 28 days duration since it was opened (Table 3).

In the present study all the CCH had knowledge about VVM, time of use of reconstituted vaccine, timing of placement of diluents inside ILRs, vaccine requiring diluents, ice pack conditioning, cabinet temperature range of ILRs and DFs, shake test, open vial policy, freeze sensitive vaccines and temperature sensitive vaccines (Table 4).

Precautions and safety measures to prevent COVID-19 infection was also maintained. Immunization waste was disposed off through outsourcing in 1 of the health facility and through safety pit in 4 of the health facility (Table 3). Periodic monitoring was done from the district level authority. The neatness and cleanliness of the vaccine store and the premises was satisfactory in all the health facility.

DISCUSSION

Proper vaccine storage and handling were important factors in preventing and eradicating many common vaccine-preventable diseases. Failure to store and handle vaccines properly can reduce vaccine potency, resulting in inadequate immune responses in patients and poor protection against disease. Patients can lose confidence in vaccines and providers if they require revaccination because the vaccines they received may have been compromised. The prevention and control of vaccine preventable disease through immunization can only be achieved if we can ensure the sero-conversion of all vaccinated children in our community by giving safe and effective vaccines, through maintenance of cold chain and good and effective practices in vaccine management.

Study conducted by Sinha et al reported that only 40% had dedicated space/room and 75% had dedicated space for syringes and diluents.⁶ In similar study Panika et al reported that 100% of the CHCs had dedicated

room/space for cold chain but none of the CHC had dedicated room/space for dry storage at facility.⁷ In Kamble et al study it was observed the all the CCPs had dedicated space/room and 83.33% of HF found to be visited by CCT.⁸ In the present study it was found that in 60% of the CCP, the ILR and DF were placed as per specified guidelines.

In the current study all the HF ice packs were correctly placed in a criss-cross pattern and 80% of the CCP had dedicated table for conditioning of ice packs. Sinha et al in their study reported that among all CCPs visited 45% CCPs had dedicated table/space for conditioning.⁶ In Panika et al study it was found only at 66.6% CHCs had dedicated table for conditioning of icepacks.⁷ In Mendhe et al study 77% CCPs had dedicated thermometers provided for each functional cold chain equipment and in 92% CCP, the temperature of CCE was recorded twice a day.9 In a study by AIIMS Patna, functional thermometers were placed inside cold chain equipment in only 28.6% of health centers and twice daily temperature recording was also observed in 78.6% of cold chain points.¹⁰ A study conducted by Naik et al in Surat city observed that twice daily temperature recording was present in all cold chain points.¹¹ In a study in Delhi, the twice daily temperature recording activities were observed in only 72% of facilities. 12 In Mallik et al study only 60% recorded temperature twice and 80% maintained temperature in optimal range.¹³ In the present study, in all the CCPs temperature was recorded twice daily including the holidays along with maintenance of the temperature in optimal range.

In the current study the vaccine vials were found to be correctly arranged within the basket in all the cold chain points. Diluents were place in the ILR in 100% of the CCP. In Choudhury et al study it was observed that in 83.33% of the cold chain points, ILR and DF were properly placed, ILR and DF were connected to functional voltage stabilizer in 75% cold chain points and a functional thermometer was placed inside every ILR and DF of all the cold chain points. ¹⁴ In the current study it was found that all the CCP had separate temperature log book for ILR and DF. In Sinha et al study it was observed that only 45% CCP had separate temperature log book for ILR and DF. ⁶ The present study found that

the contingency plans for vaccine and standard job aided were displayed in all the CCPs. In Naik et al study it was found that emergency contact number was written nearby in the same room in only 15% health centres. 11 In the Mendhe et al study it was found that 63.3% displayed contingency plan and 66.7% has displayed standard job aids.9 In this study all the CCP had updated stock register and eVIN app and maximum and minimum stock level where the wastage rate was positive, full vaccine vials were issued and the remaining were returned with proper labelling of date and time. In Bagdey et al study the wastage rate for pentavalent vaccine was 2.72%, Praveen et al study found 0% wastage of pentavalent vaccine. 15,16 In the current study all UIP vaccine and diluents were used, no frozen vaccine was found, no vaccine vial beyond usable VVM or beyond expiry date or with unreadable label were found. In Mendhe et al study vaccine vial beyond usable VVM as well as vaccine vial beyond expiry date found only in 5% CCP.9 A study by Naik et al found that in 5% UHC/CCP at Surat municipal corporation, expired vaccine vial was found in ILR and vaccine in the unusable stages of VVM found in 15% CCPs.11

In this study open vaccine vial were found in 5 CCPs, stored in ILR with proper labelling of date and time and within the usable duration, less than 28 days. In Panika et al study it was observed that in all 3 CHCs, all vaccine vials have proper readable labels, all vaccines found within expiry dates, all the vaccines with usable VVM (I and II), no vaccine found in frozen condition, open vaccine vial were stored in separate box, date and time of opening was written on the vial, all open vaccine vials were of less than 28 days duration. Sinha et al observed that in 70% CCPs open vials were correctly (separate box/zipper bag) placed inside ILR with date and time mentioned in it.

Limitation

Due to COVID situation there was lack of time to include more sample.

CONCLUSION

The present study findings concludes that most of the cold chain points scored good in respect to the parameters such as ILR and DF placement, adequate space for ice pack conditioning, updated stock register and temperature log book, availability of trained VCCH, and neat and clean ambience. The overall performance of the CCPs were good enough though with very few parameters in CCPs lagging behind and having a scope of further improvement of function by actively conducting the monitoring and supervision of the on regular basis.

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