ORIGINAL ARTICLE

Assessment of Cold Chain System for Routine Immunization of Primary Health centres of the Bhojpur district of Bihar

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Abstract

Background: Immunization is an important among activity in the Public Health Services. The vaccines are highly temperature sensitive and vaccine potency once lost cannot be restored. A well-managed cold chain will increase the efficiency of immunization and reduce vaccine wastage. An assessment of cold chain system for vaccine storage was done in the all PHCs of the study area. **Aims & Objectives**: To evaluate the cold chain practices, with particular reference to assessing the availability of cold chain equipment, vaccine storage practices, monitoring of cold chain in primary health centres (PHCs) of Bhojpur district. **Material & Methods**: A cross-sectional study was conducted at all the cold chain points of 14 PHCs of Bhojpur district during January to May 2015. A predesigned, pretested checklist was used by the trained investigators during their visits. The information was evaluated on the basis of important components related to the cold chain points. **Results**: All the PHCs had a dedicated cold chain room with sufficient number of cold chain equipment. Consolidated effective vaccine management score for cold chain points of 8 (57.1%) PHCs were average (60-79%). None of the PHCs have satisfactory score (≥ 80%). Vaccine storage practice and availability of complete RI micro-plan were found satisfactory at 12 (85.7%) PHCs. Maintenance of cold chain equipment were satisfactory at 10 (71%) PHCs. But, temperature monitoring. (5) (35.7%) and waste disposal related to routine immunization 3 (21.4%) PHCs were disappointing. **Conclusion**: The primary health centres had average performance related to the cold chain system, which is a matter of concern warranting for the cold chain monitoring. We recommend supportive supervision as the key measures in improvement of cold chain system.

Keywords

Cold Chain Equipment; Consolidated Effective Vaccine Management Score; Primary Health Centres (PHCs); Routine immunization; Vaccines; Vaccine storage

Introduction

Immunization is a crucial component of the Public Health Services. Immunization prevents illness, disability and death from vaccine-preventable diseases including diphtheria, hepatitis B, measles, mumps, pertussis, pneumonia, polio, rotavirus diarrhoea, rubella and tetanus etc. Immunization currently averts an estimated 2 to 3 million deaths every year. (1) Immunization is acknowledged among the most cost-effective and highest health-impact interventions.

India launched its first vaccine – BCG in 1962 as a part of National Tuberculosis Program. (2) The Expanded Programme on Immunization (EPI), a national programme for immunizing all children during the first year of life with Diphtheria, Pertussis and Tetanus (DPT), Oral Polio Vaccine (OPV), Bacilli Calmette Guérin (BCG) and typhoid–paratyphoid fever vaccines was launched in 1978. In 1985, the name of EPI was changed to the Universal Immunization Programme (UIP) to cover all districts in a phased manner by 1990 with a lofty goal to cover all the eligible under five children against six vaccine preventable diseases and all pregnant women with TT vaccine. (3)

The vaccines used in the UIP are highly temperature sensitive regarding their potency. The quality of vaccination services is important for achievement of the ultimate goal of disease reduction. There are many gaps in the area like storage of vaccines, temperature monitoring in routine activities. Suboptimal seroconversion rates and outbreaks of vaccine preventable diseases elsewhere were attributed to loss of vaccine potency either during transportation or storage. (4) Vaccine potency once lost cannot be restored. Hence, the backbone of the efficient immunization system is the maintenance of cold chain. Cold chain refers to the network of equipment, personnel and processes that ensures that vaccines are transported and stored at appropriate temperatures up to the point of administration, ensuring that they retain their potency. A well-managed cold chain will increase the proportion of effective vaccines that are administered and reduce vaccine wastage. Hence, the cold chain system requires attention for effective vaccination programme. There is paucity of information on this issue in the district Bhojpur of Bihar.

Aims & Objectives

To evaluate the cold chain practices, with particular reference to assessing the availability of cold chain equipment, vaccine storage practices, monitoring of cold chain in primary health centres (PHCs) of Bhojpur district.

Material & Methods

Study settings: The evaluation of the cold chain system for routine immunization programme at was conducted at all 14 PHCs of Bhojpur district of Bihar, India. The important equipment in cold chain system are mainly the electrical cold chain equipment like ice-line refrigerators (ILRs), deep freezers (DFs) and voltage stabilizers.

This district has an area of 2474 sq. kms and a population of 2,720,1555. The district has 14 PHCs. The district is served by a district hospital and 14 primary health centres. **Study design**: Cross-sectional observational study conducted during January to May 2015. **Study unit**: The cold chain system of all the primary health centres of the district were included. **Data Collection**: The ethical approval from the ethical committee of AIIMS Patna was taken prior to start the study. Prior permission was obtained from the District Immunization Officer of Bhojpur. The health centres were visited by the investigators and the investigators were imparted training for the assessment before initiation of these activities. The physical verification of the available cold chain equipment was done and their functional status was also examined during each visit by the investigators.

A predesigned and pretested checklist was used to collect the data. The information was collected from cold chain handler and medical officer in charge for routine immunization of the respective cold chain system at PHC. The information was evaluated on the basis of important aspects related to the cold chain system. These components were related with status of cold chain system, routine micro-plan, status of all cold chain equipment and their maintenance, temperature monitoring practices, vaccine storage practices, vaccine and logistics management, recording and reporting system and waste disposal activities. Storage practices of vaccines and diluents were also assessed on the recommendation about placement of heat and freeze sensitive vaccines, returned partially used and unused vaccine vial under open vial policy.

WHO based consolidated effective vaccine management (EVM) scores were given to the cold chain points of the related PHCs. 9 global criteria like vaccine arrival procedures, vaccine storage temperatures storage capacity (Cold, Dry and Transport), buildings, cold chain equipment and transport, maintenance of cold chain equipment and transport, stock management, effective vaccine delivery, vaccine management practices, MIS and supportive management systems are assessed in EVM scores. (6) WHO recommends a score of 80 % as satisfactory, 60-79% as average and below 60% as poor performance for each criterion.

The cold chain handlers available during the visit were interviewed to assess their training and knowledge regarding cold chain. The questionnaire included questions on information of the respondent related to knowledge regarding management of the cold chain including the recommended storage temperature range, use of vaccine vial monitor (VVM), use of diluents, storage in deep freezer, the shake test.

Results

Out of total 14 PHCs of the district, the trained cold chain handlers were present at 11 (78.6%) PHCs. At 10 (71.4%) PHCs, ANM were working as cold chain handlers whereas at rest of PHCs the work of cold chain handling was being done by other category of staffs such as pharmacist, dresser etc. Session wise routine micro-plan was available at 12(85.7%) out of PHCs.

Status of Functional Cold chain equipment (Electrical) at the PHCs

As the availability of cold chain equipment are concerned the non- electrical equipment were sufficient in all primary health centres. At least one of each of the electrical equipment - ILR and DF were present in 11 (78.6%) PHCs and two ILRs and DFs were available in remaining 3 PHCs. The domestic type of refrigerator and mini refrigerators were not being used for storage of vaccines and diluents at any of primary health centre.

All PHCs have separate cold chain room in which all the vaccine storage equipment were kept. The ILRs and DFs were placed away from sunlight and moisture at all the PHCs. The ILRs and DFs were properly placed 10 cm away from the wall in 12 (85.7%) PHCs and in only 7 (50%) PHCs, the ice lined refrigerators and deep freezers were kept on wooden block. The separate voltage stabilizers for cold chain equipment (ILR & DF) were present in only 6 (42.9%) PHCs (Table 1). In 8 (57.1%) PHCs, the icepacks were correctly placed in deep freezers. At 7 (50%) PHCs, all functional cold boxes were clean and dry from inside. In 11 (78.6%) PHCs, cold chain technician visited facility in previous 3 months for preventive maintenance.

Storage Temperature monitoring Practices (Functional Electrical CCE)

As shown in Table 2, functional thermometer were placed in only 4 (28.6%) PHCs for every functional electrical cold chain storage equipment (ILRs and DFs). However, in 8 (57%) PHCs the cabinet temperature was within recommended range for ILR and only 6 (43%) for DFs. Separate standard temperature log book was available for ILR and DFs at 7 (50%) and 4 (28.6%) PHCs respectively. In 11 (78.6%) PHCs, temperature was noted twice daily for ILR and in case of DFs twice daily recording was being done at 9 (64.3%) PHCs. The temperature log book for ILRs and DFs were reviewed by Medical officer only at 8 (57.1%) PHCs. At 9 (64.3%) PHCs the ILRs were frost free but in only 5 (35.7%) PHCs, the DFs were frost free. Records of power failure and defrosting were maintained in only one PHC (7.1%). However, in all of the PHCs, there were regular power supply and back-up generator services.

Status of Vaccine Storage Practices

In 10 (71.4%) PHCs, the vaccines were correctly arranged from bottom to upwards as per norms (Table-3). At 3 (21.4%) PHCs, RI vaccines were stored inside DFs. Expired vaccines were stored in DF at one PHC. The VVM status of stored vaccines were within the usable stages at most of the PHCs i.e. 12 (85.7%) whereas at 2 PHCs the oral polio vaccines of stage 3 were stored in DF. Reconstituted vaccines were not stored in any of cold chain equipment at any place. At 3 (21.3%) PHCs, items other than vaccines like anti rabies vaccine, anti - snake venom etc. were stored inside ILR. At 13 (92.8%) PHCs, opened vials of vaccines were stored in ILRs and out of these at 12 PHCs, they were placed separately in ILR whereas at one PHC open vial vaccines were kept together. Returned unused and used vials under open vial policy were distributed on priority basis on next session day in all PHCs. The updated stock register were available at only 6 (43%) PHCs.

The table 4 depicts the summary of consolidated Effective Vaccine Management scores for the indicators clubbed into eight criteria. As per WHO recommendation, the individual scores should be

more than 80% for a satisfactory performance. Consolidated score of 8 (57.1%) PHCs was between 60-79% and three PHCs out of these eight were scored more than 70%. As regarding the various activities related to cold chain points in the district (radar chart for EVM score for the district, fig1), vaccine storage practice (85.7%), availability of complete RI micro-plan (85.7%), availability of trained cold chain handlers (83.3%) and maintenance of cold chain equipment (71%) were satisfactory. But activities like temperature monitoring (37.2%) and waste disposal related to routine immunization (21.4%) were very disappointing.

Discussion

Childhood immunization is among the most cost-effective health interventions and India has one of the largest immunization programmes in the World. All the vaccinated children are considered immunized only when their sero-conversion level is within the accepted normal value. Sero-conversion of the individuals is affected by various internal and external factors. The external factors are related to the vaccines such as maintenance of cold chain equipment, vaccine storage and temperature monitoring. These are very critical for determining the potency of vaccines. Hence, the cold chain system remains a highly vulnerable element of any immunization programme.

This study focused on investigating the availability and maintenance of electrical cold chain equipment, temperature monitoring and vaccine storage practices in Bhojpur district of Bihar. In present study, 78.6% of PHCs had availability of trained cold chain handlers. Presence of ILR and DF are one of the basic cold chain equipment which any health facility needs to have for efficient cold chain maintenance. (7) In this study, all the PHCs had sufficient number of functional ILR and DF and this showed better status than the observations made in different areas of India. (4,8,9,10) Exposure to 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 core temperature of ILR and deep freezer. This causes exposure of vaccines to higher temperature than required. In the present study, there was a separate room dedicated for cold chain equipment in all the PHCs of the district. The deep freezer and ice-line refrigerators were placed away from the direct sunlight at all places, but were placed at least 10 cm away from the wall at 85.7% places. This was similar to the finding reported in several other studies. (7,9,10).

As per the standard norm, the present study showed that in 6 PHCs (42.9%), separate voltage stabilizer was attached each to deep freezer and ILR. Shortage of voltage stabilizers was also reported in several other studies (10,11,12,13).

The potency of vaccines depends on maintaining the cold chain within a prescribed temperature range of 2-8°C during storage and transport. 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. Thus, the ILR and deep freezers, each should have a separate functional thermometer and updated temperature record book. In the present study, functional thermometer in ILRs and DFs was available only in 4(28.6%) PHCs. But, temperature was being recorded twice a day for both deep freezer and ILR in two-third of the health centres in separate temperature record books which was not indicating the real fact regarding the temperature monitoring of electrical cold chain equipment for vaccine storage. This was lower as compared to other studies conducted in India. (8,10,11,13)

The temperature in the ILR/freezer can also rise due to presence a thick layer of ice around the freezer or along the walls and bottom of ILRs. It is therefore necessary to defrost them periodically. This should be done if the ice in the freezer is >5 mm thick. The present study showed that defrosting of ILRs and deep freezers was very irregular and recording of the temperature record in register was done only in one of the health centres. However, on observation, the ILRs were frost free in 9 (64.3%) PHCs, but for DFs, it was frost free only in 6 (35.7%) centres. The similar practice for defrosting and maintenance of its record for ILRs and DFs were reported in other studies. (10,11)

Vaccines lose their potency due to exposure to excessive heat or excessive cold and were not effective if administered to the beneficiary. Freeze sensitive vaccines like T-series vaccines (DTP, TT, Pentavalent) and Hepatitis-B may be damaged by exposure to freezing temperatures and hence it is crucial to store them between +2°C and +8°C temperature. (14,15,16) Diluents vials also must not be frozen as it may cause the glass to crack and cause contamination of the content. In the present study, vaccines were arranged as per guideline in

approximately in three fourth of the centres. OPV was stored in DF only in 3 (21.4%) places. These finding of the study were in similar to the results of the studies reported in various places. (8,10,11) It is also important that VVM status does not indicate if a vaccine has been frozen. Thus, the cold chain handlers need to understand the importance of this arrangement, as impotent vaccines give a false sense of security against vaccine preventable diseases, which a child would contract later on despite the vaccination.

The concept of Vaccine Vial Monitor (VVM) was conceived in 1997 and formally introduced for all UNICEF procured OPV vials in 1996 and slowly expanded to other heat sensitive vaccines. VVM technology was introduced for heat labile vaccines with two-fold intent: to reduce vaccine wastage and to identify heat damaged stock thus preventing administration of less efficacious vaccine to the beneficiaries8. In our study, the vaccine stored in the ILR at 12 (85.7%) PHCs were within usable VVM stage. Similar results were reported from various studies where vaccines were in usable condition. (8,9,17,18)

Lyophilized vaccines such as measles vaccines need to be kept cold and to be used within 4 hours after they have been reconstituted. Otherwise, such vaccines lose stability and are at increased risk of bacterial contamination. No reconstituted vaccines were stored in the ILR in any places as reported in the study.

As per the guidelines, diluents are to be stored in ILR. If there is space constraint, it can be stored outside. (19) But, they have to be cooled at least 24 hours before use to ensure that both vaccines and diluents are at +2° to +8°C when being reconstituted or else might lead to thermal shock. In our study, diluents were stored in ILR in 92.9% of centres at least 24 hours before use as informed by the cold chain handlers. As per the Multi Dose Vial Policy (MDVP)/Open vial policy guidelines, the multi-dose vials of vaccines except reconstituted vaccines of BCG, Measles, JE opened in a fixed or outreach session can be used at more than one immunization session up to four weeks provided that a) they are within expiry date, b) the vaccines are stored under appropriate cold chain conditions both during transportation and storage in cold chain storage point, c) the vaccine vial septum has not been submerged in water or contaminated in any way, d) the vaccine vial monitor (VVM) should be within usable stage and e) aseptic technique has been used to withdraw all doses. (6) In the present study, open vial vaccines were collected, stored and reused on priority basis in all the centres.

Conclusion

As per our study, all the centres have dedicated cold chain room with the availability of functional ILR and DF. However, none of the centres had satisfactory performance based on the WHO criteria. As regarding the various activities related to cold chain points in the Bhojpur district like vaccine storage practice, availability of complete RI micro-plan, availability of trained cold chain handlers and maintenance of cold chain equipment were found to be satisfactory. The cold chain monitoring status in the district is inadequate to ensure proper vaccine storage as the activities like temperature monitoring and record maintenance were not proper. There is a grave concern on the status of the cold chain monitoring since it can cripple the immunization program. Waste disposal related to routine immunization needs much attention.

Recommendation

It is recommended that continuous training and supportive supervision of the cold chain system at the primary health centres should be taken up in regular manner which is the key measures to address the findings of this study.

Authors Contribution

All authors have contributed equally in the study.

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Tables

TABLE 1 STATUS OF FUNCTIONAL COLD CHAIN EQUIPMENT (ELECTRICAL) IN THE PHC

Functional Equipment	ILR	DF
	No (%)	No (%)
Placed away from sunlight, moisture	14 (100)	14 (100)
Placed 10 cm away	12 (85.7)	11 9 (78.6)
Wooden block	7 (50.0)	7 (50.0)
Separate VS	6 (42.9)	6 (42.9)

TABLE 2 STORAGE TEMPERATURE MONITORING PRACTICES (FUNCTIONAL ELECTRICAL CCE)

Functional Equipment	ILR	DF
	No. (%)	No. (%)
Functional thermometer placed inside every functional equipment	4 (28.6)	4 (28.6)
Cabinet temperature within recommended range	8 (57.1)	6 (42.9)
Separate standard printed temperature log books available	7 (50.0)	4 (28.6)
Temperature records noted down twice daily	11 78.6)	9 (64.3)
Log books reviewed by facility in charge at least once every week	8 (57.1)	8 (57.1)
Frost free	9 (64.3)	5 (35.7)
Record of power failure maintained in temperature log books	1 (07.1)	1 (07.1)
Records of defrosting maintained in temperature log books	1 (07.1)	1 (07.1)

TABLE 3 STATUS OF VACCINE STORAGE PRACTICES

	Yes (%)
All vaccine vials correctly arranged in order from bottom towards upwards (as per norms)?	10 (71.4)
RI vaccines stored inside DF	3 (21.4)
Vaccines stored are within expiry dates	13 (92.8)
VVM status of stored vaccines is in usable stage (Stage I & II)	12 (85.7)
Reconstituted BCG, Measles or JE vaccines found stored	0

Items other than vaccines used for routine immunization stored inside ILR	3 (21.4)
All diluents placed inside ILR (at least for next session day)	13 (92.9)
Opened vial of any vaccine stored inside any ILR	13 (92.9)
If yes, are they stored separately inside ILR?	12 (85.7)
Are these returned unused vials distributed on priority on next session day?	14 (100)
Whether Stock register has been updated till last session day?	6 (42.9)

TABLE 4 SUMMARY OF CONSOLIDATED EVM CRITERIA INDICATOR SCORES

Category	No. Of PHCs (%)
Satisfactory Performance (80% &>)	0
Average (60-79%)	8 (57.1%)
Poor (<60%)	6 (42.9%)

Figures

FIGURE 1 EVM CRITERIA SCORE OF BHOJPUR DISTRICT