Assessment of functioning and effectiveness of cold chain in Primary Health Centres of Bangalore Urban- North

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ABSTRACT

INTRODUCTION: Child immunisation is among the most cost-effective ways of preventing premature child deaths. The potency of vaccines, crucial for vaccine efficacy, is dependent on effective management of the cold chain at all levels of vaccine handling. India's immunization program is one of the largest in the world. However, full immunization coverage still stands at 61% only. Since there were gaps in immunization coverage and a situation of high morbidity and mortality among under five children, India decided to declare the year 2012-13 as a year of "Intensification of Routine Immunization" for effective vaccine management.

OBJECTIVES*:* To assess functioning and effectiveness of cold chain in PHCs.

METHODS: This is a cross sectional study in which 30 Primary Health Centres that were allotted, 27 were studied on immunization days (Thursday). Mentors were trained and data was collected using observational checklist.

RESULTS AND DISCUSSION*:* Among the 27 Primary Health Centres studied, 1 centre didn't have Ice line refrigerator or Deep freezer, 13 centres didn't have deep freezer. In 22 centres, Cold Chain equipment were attached to stabilizer, 7 centres placed equipment as per standard norms, 3 centres had not maintained temperature charts, 3 centres didn't have thermometers. 10 centres showed discrepancy in recorded temperature. Vaccines at the session site were in zipper pouch in vaccine carrier at 23 centres. There are a lot of weaknesses and gaps in cold chain maintenance, thus arising the doubt of potency/efficacy and safety of vaccines administered. To improve the situation constant monitoring and supervision, periodic training of personnel is necessary.

KEY WORDS: Cold chain equipment; immunization; supervised monitoring; vaccines

Introduction

Immunization is one of the most cost effective health investments and proven tool for controlling and eliminating life-threatening infectious diseases (known as vaccine preventable diseases). Globally it is estimated to avert over between 2-3 million deaths each year (1). India's immunization program is one of the largest in the world in terms of quantity of vaccines used, beneficiaries, number of vaccine sessions organized, the geographical spread and diversity of area. Regrettably, however, full immunization coverage in the country continues to be sub-optimal, standing at a mere 60% at the national level (2). There are many states where full immunization coverage is less than 50%. On the other hand there are states having coverage above the national level yet the coverage there is either stagnant or is declining. Government of India is annually spending more than 1500 crore on universal immunization program and pulse polio (3). Gaps in the immunization coverage result in low return on this investment, besides a situation where morbidity and mortality among children continues to be unacceptably high.

In view of the above, it was decided to declare the financial year 2012-13 as the year of 'Intensification of Routine Immunization' in which all efforts were made to improve full immunization coverage throughout the country. This declaration was in consonance with the resolution of all countries in South-East Asian region to declare 2012 as the year of "Intensification of Routine Immunization"(4).One of the major activities proposed during 2012-13 as the year of "Intensification of Routine Immunization" was the effective vaccine management exercise in all priority states to assess and strengthen cold chain and vaccine management (4).The cold chain is a system of storing and transporting vaccines at recommended temperatures from the point of manufacture to the point of use. The key elements of the cold chain are:

1. personnel-to manage vaccine storage and distribution
2. equipment- to store and transport vaccines and to monitor temperature
3. procedure- to ensure that vaccines are stored and transported at appropriate temperatures (5).

Reconstituted BCG, measles, JE vaccines are the most sensitive to heat and light. Also there is risk of contamination with staphylococcus aureus leading to Toxic Shock Syndrome. And therefore they should be used within 4 hours of reconstitution. Hepatitis B and all T series vaccines lose their potency if frozen. Deep freezers (DF) maintain a cabinet temperature between -15 to -25 ^{0}C.Ice lined refrigerator (ILR) maintain a cabinet temperature between $+2^{0}$C to $+8^{0}$C and are used to store all Universal Immunization Programme (UIP) vaccines at the Primary Health Centre (PHC) level. ILRs can keep vaccines safe with as little as 8 hours continuous electricity supply in a 24 hour period (5). At PHC level, deep freezers are used only for preparation of ice packs and are not to be used for storing UIP vaccines.

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In India, UIP was introduced since 1985 with objective of immunization of pregnant women with two doses of tetanus toxoid and immunization of children in their first year of life against six vaccine preventable diseases (6). Achieving this objective depends on quality of vaccines used. To preserve its potency and safety, cold chain has to be maintained at all levels. Those involved in this to be skilled and equipped regarding condition of storage and transportation as well as temperature monitoring.

In Karnataka, there has been a decline in full immunization coverage between National family health survey (NFHS) - 2 (60%) and NFHS- 3 (55%) (7).

Reasons for poor coverage were said to be poor monitoring and lack of feedback on reported data in monthly meetings at various levels by routine immunization managers, poor usage of the standard tools to track, document and report immunized children by health workers at PHC/Sub centre level. There is a disarray of documentation with poor quality coverage of data, lack of effective and supportive supervision of the program, failure to assess output of the program. Realizing the need for additional supporting monitoring of the program, State institute of health and Family welfare (SIHFW) in collaboration with UNICEF has developed a model by involving medical colleges for this activity. Each mentor will do field visits on selected Thursdays (thrice a month) to supervise and monitor various components of routine immunization activities viz.; the adherence to micro planning for conducting immunization session, quality of practices, session monitoring, quality of reports, hands on training to service providers, identification of training needs, availability of equipment and supplies, maintenance of cold chain equipment, etc. Thus, here we have assessed the status of cold chain monitoring which was one of the components of supportive supervision.

Objective: To assess functioning and effectiveness of cold chain in PHCs.

Materials and Methods:

Study design: Cross sectional study.

Setting: 27 PHCs under SIHFW in Bangalore district.

Methodology: Study was part of programme to support district health authorities by monitoring and providing supportive supervision for the immunization related activities. Bangalore district was one of the selected districts in terms of densest urban district. A list of 30 PHCs were given by SIHFW, out of which 27 centres were studied. PHCs were visited on Thursdays (immunization day). The mentors were trained and data was collected using observational checklist to ascertain cold chain maintenance of vaccines and by related documents. Data collected were on availability of Cold Chain Equipment (CCE) and its placements, twice daily monitoring of temperature recordings and its variation on the day of the visit, presence of functional thermometer, record of power failures and periodic defrosting, periodic check of temperature log books by facility in charge. Information on storage conditions of vaccine and diluents, its correct placement in ILR, correct placement of ice packs in DFs, presence of any food items or any other non-recommended items found in CCE. At the session site, presence of vaccines in zipper bag in the vaccine carrier and written time on reconstituted BCG, measles vaccine was recorded. Collected data were coded and entered in excel sheet and analyzed using trial version of SPSS 20.

Results:

27 PHCs were included in the study. 1 PHC (3.7%) out of 27 did not have ILR or DF. 13 PHC's (48.1%) out of 27 did not have DF. CCEs were attached to electric outputs through voltage stabilizer in 22 PHC'S (81.5%) (Fig.1). Placing of ILRs and DF 10cm away from the wall or adjoining structures were in 7 PHCs (25.9%) (Fig 1). The CCEs were kept away from direct sunlight in all the centres. Temperature chart with 2 entries was maintained in 23 centres (85.2%) (Fig. 2).Three of the centres did not have functional thermometer (Fig.1) where the temperature was recorded from display. On the day of the visit, discrepancy in ILR temperature was noted among 10 (37%) PHCs (Fig.2) , where the temperature was less than +2 deg c in 4 centres and more than +8 deg c in 6 centres and with one centre having power fluctuation since two days. Food articles were not present in any of the PHCs. Ice formation of more than 5mm in CCEs were found in 17 centres (62.9%) (Fig.1) and water logged ILR in one centre, suggestive of lack of regular defrosting. Heat sensitive vaccines were correctly stored. Freeze sensitive vaccines were not correctly stored in 9 PHCs where they were placed at the bottom of the ILR. Power failure was present for more than 24 hrs in 1 centre. Uninterrupted Power Supply backup was present in 3 of the centres. Actions taken during these power failures were not documented in 19 centres (63%) (Fig. 2). Ice packs in DFs were not placed in criss-cross manner in 9 centres (33.3%) (Fig. 3).

At the session site there was no shortage of any of the vaccines or the diluents. All the vaccines were found in the usable condition with respect to vaccine vial monitor (VVM). The vaccines at the session site were in the zipper pouch in vaccine carrier in 85.2% (23) (Table 1).Time of reconstitution was found to be written on reconstituted BCG and measles vials in 15 centres (55.6%) (Table 1).

Flaws noticed during the immunization session were immediately corrected and the importance was emphasized to the health worker and the observations were discussed with the medical officer.

Figure 1: Placement and functioning of ILR's and DF's

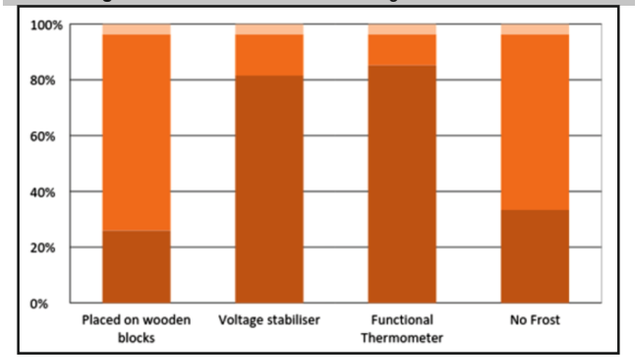

Figure 2: Monitoring of temperature log books

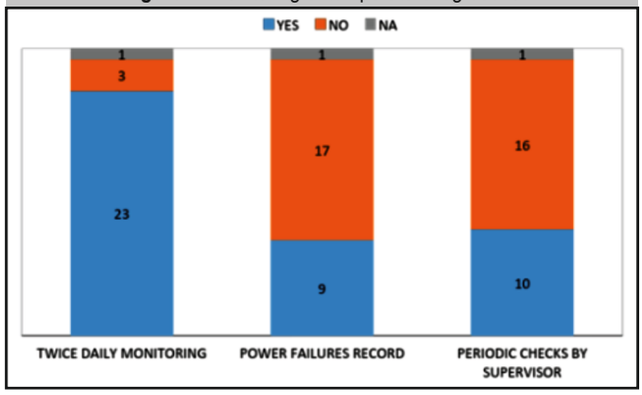

Figure 3: Maintenance of ILR

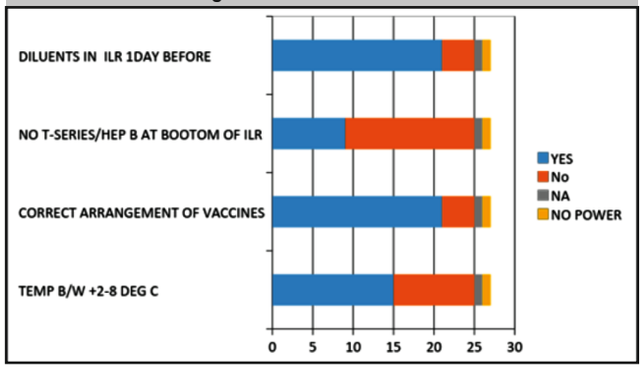

Figure 4: Functioning of Deep Freezers

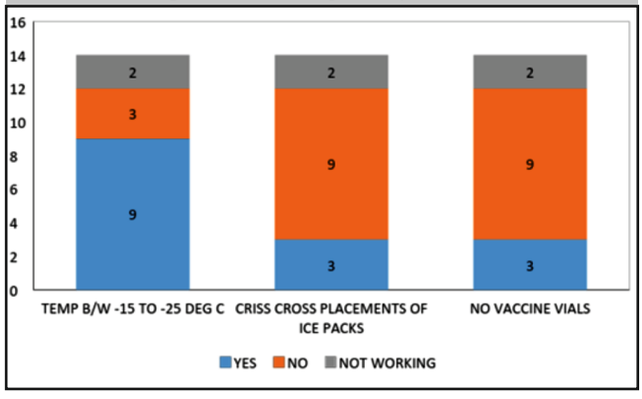

Table: Observation of placement of vaccines in vaccine carrier and time of reconstitution

	Yes	No
Vaccine vials in zipper bag of vaccine carrier	23 (85.2)	04(14.8)
Time of reconstitution written on BCG, Measles vials	15 (55.6)	12 (44.4)

Discussion

The purpose of the study was to provide supportive supervision and monitoring of routine immunization. It is a process of helping staff to continuously improve their knowledge and skills, thus improving work performance. It is a two way communication and builds team approach that facilitates problem solving.

One of the PHC was conducting immunization sessions without CCEs where they had to get the vaccines from mother PHC. Transporting of vaccines before and after immunization session increases the risk of vaccine to lose its potency thus increasing its wastage. It was good to note that power source was permanent (UPS backup) in 11% which can be extended to other centres. Non functional thermometer (11.53%), lack of temperature monitoring charts (11.1%) and documentation of irregular power supply is one of the critical elements in maintaining the potency of vaccines.

The degree of implementation of cold chain with respect to presence of ILR was 96.3% and DF was 51.9%.The study by S. Sachdeva and U. Dutta (8) showed the presence of ILR as 6.25%. Our study showed an insufficient supervision of CCEs of 59.3% whereas it was 25.9% in a study by Jerome Ateudjieu et al (9). It was noted that lack of temperature maintenance of ILRs and DFs and monitoring was only 11.1% in our study, compared to 71.8% observed by S.Sachdeva , U. Dutta and 40.7% by Jerome Ateudjieu et al. Freeze sensitive vaccines (T series and hep.B) were not correctly stored in 9 (33.3%) PHCs, where they were placed at the bottom of the ILR. The consequences of not keeping the vaccines at the right temperature (either heat or cold) can be disastrous. Once vaccine potency is lost, it cannot be regained. This leads to wastage of expensive vaccines. Moreover, children and women who receive such a vaccine are not protected. All vaccines are damaged by temperatures more than $+8^{0}$ C, whether they are exposed to a lot of heat in a short time or a small amount of heat over a long period (frequent opening of lid of ILR).

Various loopholes in the system have been noted from this study as a risk factor for vaccine potency. The project experiences were used for further strengthening the immunization programme. Some interventions like constant supervision, training of professionals in charge, availability of cold chain tools and its maintenance in case of breakdown can reduce the gaps. Furthermore, strategies like instalment of UPS, annual maintenance contract, developing thermo-stable vaccines could improve the vaccine potency.

Limitations

If periodic follow-up supervision of CCEs in the PHCs is done, then it will throw light on adoption of suggested corrective measures which will pave way towards further improvement.

Conclusion

There are a lot of weakness and gaps in cold chain maintenance in the country, thus raising the doubt of potency/efficacy and safety of vaccines administered. This in turn increases the cases of vaccine preventable diseases and adverse events following immunization. To improve this situation, we recommend:

- Constant supervision of CC equipment and periodic check by supervisors.
- Identify and address factors leading to failure of CC monitoring.

- Periodic training of personnel in CC monitoring and strengthening their skills.
- Instalment of UPS for power back-up and assistance to provide repair when required
- Routine maintenance of CCEs.

Acknowledgments

The author acknowledges the support and cooperation of SIHFW, Directorate of Health and Family welfare services, Bangalore. The authors are indebted to Dr Santhosh Shirol for his enormous support.

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