

## Assessment of cold chain system in tribal PHCs of Visakhapatnam

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### Abstract

**Introduction:** Cold chain system plays a crucial part in maintaining the potency of the vaccines under the Universal Immunization Programme. Each year full immunization prevents approximately 4 lakh deaths among children under five years of age from vaccine preventable disease in India. Due to accessibility issues among others, cold chain management & immunization related issues are quite common in tribal areas.

**Methodology:** A cross sectional study was conducted in 8 PHCs located in the tribal areas of Visakhapatnam during April May 2015 to assess the cold chain system. Out of 36 tribal PHCs, 8 were selected using simple random technique. Information about the cold chain at the PHC as well as the outreach session sites was obtained using routine immunization monitoring formats provided by the Ministry of Health & Family Welfare.

**Results:** ILRs and DFs were present and placed properly in all the PHCs with functional thermometer. Frost of > 5 mm was observed in the ILRs in 62.5% of PHCs. At all the session sites (100%), vaccine vials and diluents were placed in a plastic cover (zipper bag). Conditioned ice packs were seen in one session site only.

**Conclusion:** The cold chain management is satisfactory in the tribal areas of Visakhapatnam, although there are certain gaps and issues which can be overcome by regular supervision by the in charge officer & monitoring at the outreach site etc.

**Keywords:** Cold Chain, ILR, Deep Freezer, Tribal.

### Introduction

Immunization is one of the most cost effective intervention as it provides direct and effective protection against preventable morbidity and mortality among under five children.<sup>(1)</sup> India has been one of the first countries to adopt the World Health Organization's Expanded Programme on Immunization (EPI). The program started globally in 1974 and was initiated in India in 1978 which was renamed as Universal Immunization Programme (UIP) in 1985.<sup>(2)</sup> Each year full immunization prevents approximately 4 lakh deaths among children under five years of age from vaccine preventable disease in India. However close to 75 lakh children every year miss the benefits of childhood vaccinations.<sup>(3)</sup>

Successful immunization programs are built on functional end to end supply chain, logistics system and programmatic management<sup>(4)</sup> and periodical assessment of immunization coverage and analysis of factors contributing to drop outs and left outs. Logistic support is critical to immunization services to ensure

- i. The availability of appropriate equipment, and
- ii. Adequate supply of high quality vaccine and one of the key areas of logistic support is Cold chain management.<sup>(5)</sup>

Tribal areas are located in hilly terrains far from center and with difficult access. Logistic support mainly cold chain maintenance and its sustainability is a challenge in tribal and far to reach areas and sometimes have to compromise on the quality of service delivery.

Therefore this study was planned to assess the cold chain system in tribal areas of Visakhapatnam district.

### Methodology

It is a cross sectional study conducted to assess the cold chain system in Primary Health Centres located in the tribal areas of Visakhapatnam district. The study was conducted during April and May, 2015. Out of total 36 tribal PHCs 8 were selected using simple random technique. Immunization sessions are held twice in a week, i.e. on Wednesday and Saturday. Therefore the PHCs were visited twice in a week, once to observe the cold chain at the PHC i.e. on Wednesday and again on Saturday to observe the outreach sessions conducted in villages of the PHC as per the action plan.

### Study tool

Routine immunization monitoring format provided by the Ministry of Health and Family Welfare was used for collection of necessary data.<sup>(6)</sup> This consists of three formats. Among the three, Format I is "The Routine Immunization PHC/CHC supervision checklist" which consists of structured questionnaire under 6 parts. The 2<sup>nd</sup> part i.e. section 6, 7, 8 and 9 is on observation of cold chain. These four sections illustrate the observations on maintenance of ILRs, DFs and the temperature log books.

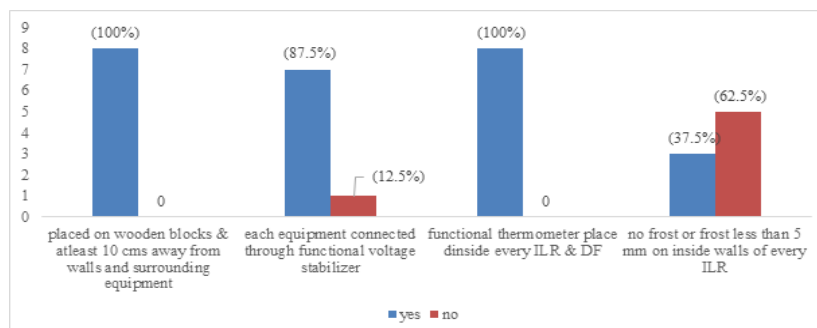
The second Format is "Routine Immunization session site supervision checklist". It consists of questions on session site observation among which those related to cold chain management (Q. no. 5,6,7,8, 10 & 11) were

included in this study. Statistical Analysis: Data was analyzed using MS Excel.

## Results

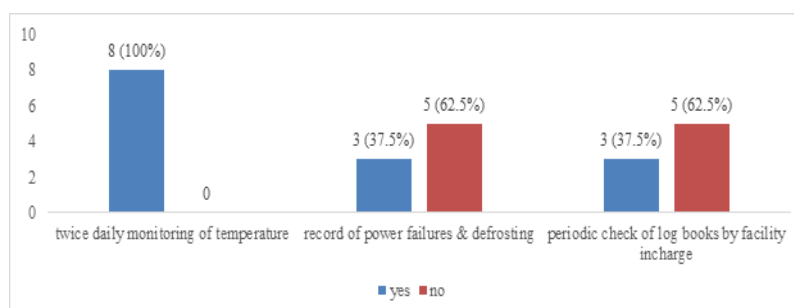
The results include observation of cold chain room in 8 PHCs and observation of 8 outreach sessions. Fig. 1 shows that in all the 8 tribal PHCs, ILRs and DFs had

wheels supporting the equipment. They were placed at least 10cms away from walls and surrounding equipment. A functional voltage stabilizer was connected to the equipment at all PHCs except for one. Similarly functional thermometer was present both in ILR and DF in all the 8 PHCs. However in 5 PHCs (62.5%) frost of > 5 mm was observed in the ILR.



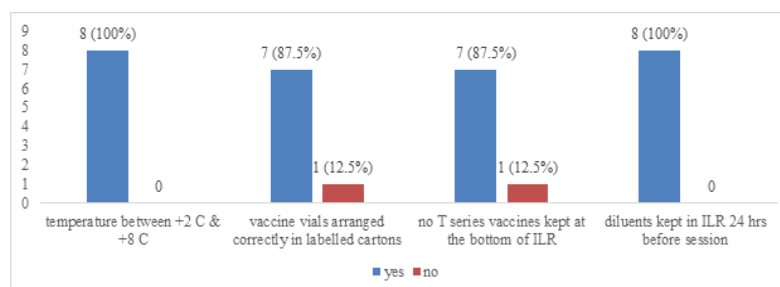
**Fig. 1: Distribution of PHCs according to the condition of ILRs and DFs (Assessment of cold chain equipment and its maintenance in PHC)**

Twice daily monitoring of temperature was being done in all the 8 (100%) PHCs as shown in Fig. 2. It also shows that in 5 PHCs (62.5%) recording of power failure & defrosting was not done. Similarly periodic check of log books by the facility in charge was not done in 5 (62.5%) PHCs.



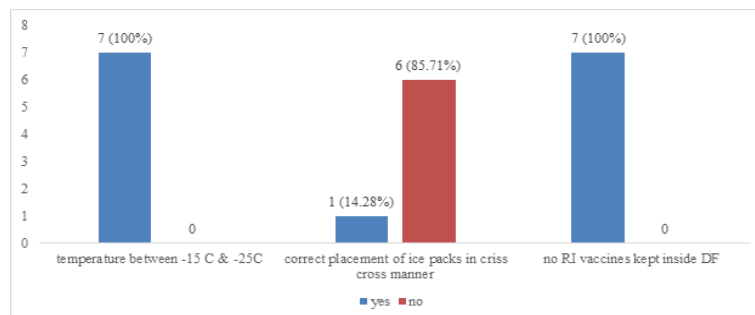
**Fig. 2: Distribution of PHCs according to maintenance of temperature log books (n = 8)**

Fig 3 shows that in all the 8 (100%) PHCs ILRs had +2° C to +8° C temp. In one PHC, Sunkarmetta which was newly established, though ILR and DF were present, vaccines were still being brought from parent PHC. In all the remaining 7 (87.5%) PHCs vaccine vials were arranged correctly in labeled cartons, diluents were kept in the ILR itself and no T series vaccines were kept at the bottom of ILR.



**Fig. 3: Distribution of PHCs on the basis of temperature maintenance & vaccine arrangement in ILR (n = 8)**

The Deep Freezer in PHC Killokada was not functioning at the time of visit. The ice packs were kept in the domestic refrigerator at the time of visit. In the remaining 7 PHCs, -15° C to -25° C temperature was maintained in the deep freezers. Correct placement of ice packs (i.e. criss cross manner) in the deep freezers was not seen at 6 PHCs. No Routine Immunization vaccine was stored in any of the deep freezers. (Fig. 4)



**Fig. 4: Distribution of PHCs on the basis of temperature maintenance and ice-pack arrangement in Deep freezer (n = 7)**

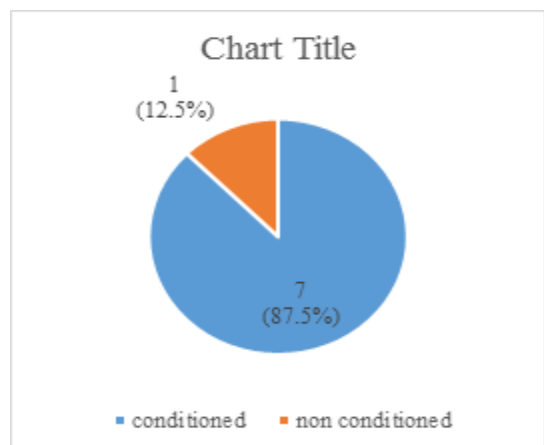
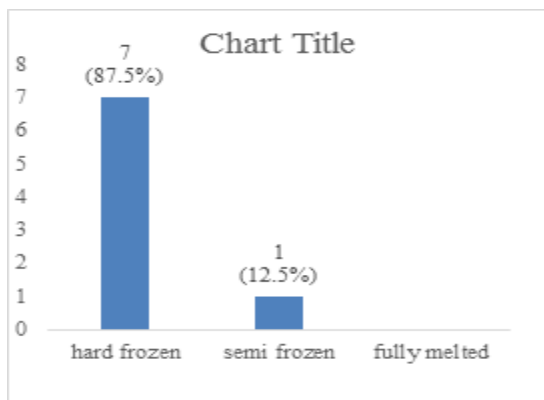
**Maintenance of cold chain at outreach session:** At all the session sites (100%), vaccine vials and diluents were placed in a plastic cover (zipper bag). None of the DPT/ Pentavalent vaccine vials were in frozen state in the sites visited. At all the 8 session sites (100%), VVM on t OPV/ b OPV was found in usable stage only. In all the 8 (100%) session sites observed, the vaccine carrier had 4 packs in it however conditioned ice packs were seen in one session site only (Fig. 5 & 6), rest of the places it was hard frozen.

**Discussion**

MoH & FW have formulated guidelines regarding management and maintenance of cold chain equipment which states that ILRs and Deep Freezers must be placed in a separate, well ventilated, airy room away from direct sunlight, wind or rain and at least 10cms away from the walls and from each other. Each equipment must be connected to the mains through its own independent voltage stabilizer with proper earthing.<sup>(6,7)</sup> Equipment must be leveled and placed on blocks or stand. In this study cold chain equipment was well placed in all PHCs except for one and also was connected to a functional stabilizer. This finding is in contrast to the results of some studies conducted in urban areas<sup>(8-11)</sup> which reported very less percentage of PHCs in urban areas actually using a stabilizer. Study by Jyothi et al<sup>(12)</sup> reported although 81.5% of the PHCs in her study had a voltage stabilizer, very less percentage of PHCs (25.9%) had the equipment properly placed in the PHCs. Alcohol stem thermometers, used for measuring the temperature of the ILR and DF are very sensitive and should be kept in between the freeze sensitive vaccines inside the basket of ILRs.<sup>(6,7,13)</sup> In this study all the PHCs had alcohol stem thermometers. Studies<sup>(8,11,12)</sup> have also reported that majority of the PHCs had functional thermometer.

Frost formation is a sign of malfunctioning of the equipment. It is recommended that the appliance be defrosted every month or earlier if the frost thickness on the inner wall is more than 5mm.<sup>(6,7)</sup> As per this study findings, in 75 % of the PHCs, cold chain equipment was maintained well with no frost or frost < than 5mm. Similar results have been observed by other studies.<sup>(8,11,12)</sup> The above observation indicates that although in majority of the places the cold chain equipment is maintained properly there are still some places where there are gaps in maintenance such as use of stabilizer or thermometer, in order to avoid damage to the vaccines. Timely defrosting increases the efficiency of the equipment.

As per the guidelines, the temperature in the ILR and Deep Freezer must be monitored twice daily and recorded in the log book. ILR and Deep Freezer each should have a separate thermometer and record book. Even power failures and defrosting should be recorded



**Fig. 5 & 6: Distribution of session sites according to the condition of ice packs in the vaccine carrier (n = 8)**

in the log books. The temperature in the ILR must be maintained at +2°C to +8 °C and deep freezer must be maintained at – 15° C to -25° C. A break in the cold chain is indicated if the temperature rises above +8 °C or falls below +2° C in ILR and above – 15° C in deep freezer. Neither vaccine nor diluent must be stored in the DF. Ice packs must be arranged in a criss cross fashion inside DF with space for air circulation.<sup>(6,7)</sup> In this study the temperature in the ILR was maintained well in all the 8 PHCs (Fig. 2). However in some of the PHCs recording of power failure, defrosting was not done and periodic check of log books by the facility in charge was not done. Power failures in peripheral hospitals or facilities located in far off places are not uncommon. Non documentation of the power failure/defrosting is a gap in the services provided and it is the responsibility of the Medical Officer to ensure maintenance of potency of vaccines in any adverse situation.

Vaccines vary in terms of their sensitivity to changes in temperature. Most vaccines lose their potency once exposed to heat above 8° C. Some vaccines lose their potency when exposed to freezing temperatures and hence must be stored at or above 2° C.<sup>(14)</sup> Such vaccines when administered to the beneficiaries, may not provide adequate immunity, moreover there is possibility of reactions. However for success of the program and to avoid any kind of adverse events, at no place the arrangement of the vaccines or the diluents and maintenance of temperature should be compromised. In majority of the PHCs in this study vaccine vials were arranged correctly in labelled cartons. Also the T series vaccines and diluents were properly placed (top position) in the ILRs. As per the findings of other studies. Vaccine vials were correctly arranged in labeled cartons and were kept at appropriate place in the ILR in more than half of the facilities. However Poor documentation for power failure and defrosting status was noted by some studies.<sup>(8,11,13)</sup> Also in all the DFs, except for one PHC, the recommended temperature was maintained. Correct placement of ice packs were seen in 6 PHCs indicating that the cold chain maintenance staff must be sensitized periodically regarding the correct placement of ice packs inside DF. Similar results were observed by Jyothi et al.<sup>(12)</sup> No RI vaccines were kept inside DF in any PHC.

### Vaccine Storage Conditions At The Outreach

Observation of outreach session for maintenance of cold chain reveals that at all session sites vaccine vials and diluents were placed in a plastic cover (zipper bag).

In order to prevent the vaccine label from getting wet, vaccines must be kept in a plastic cover before being kept in the vaccine carrier.<sup>(7)</sup> Similar reports were observed by various studies.<sup>(11,15,16)</sup> To maintain the cold chain at the outreach, the vaccine carrier with four ice packs is recommended to carry the vaccines and ensure their potency.<sup>(7)</sup> In the present study vaccine carrier with 4 ice packs were present at all the session sites (100%). Such practice is followed in many places as reported by

many studies.<sup>(11,16)</sup> Even small gap in the maintenance of cold chain questions the efficacy of the potency of the vaccine and the immunity it provides. As per the guidelines, the frozen ice packs must be conditioned before they are placed in the vaccine carrier. Conditioning means the frozen ice packs are kept in the open until there is water in the ice packs which can be checked by shaking the ice pack and listening for movement of ice inside the ice pack.<sup>(6,7)</sup> Conditioning is necessary to prevent the damage to the freeze sensitive vaccines. Therefore it is understood that ice packs should not be hard frozen but should contain ice and some water while in the vaccine carrier. In this study, except for one session site, in all the remaining places ice packs were hard frozen, which means that the concept of semi frozen ice packs is not known to the vaccinators and at 1 site fully melted ice pack was found. This indicates that the cold chain handler as well as the ANM need to be educated by the Medical Officer regarding the importance of conditioning and the effect it would have on freeze sensitive vaccines if not properly followed. Repeated supervision by the Medical Officer incharge and supervisors during the distribution of vaccines on session days will help in following correct procedures.

### Conclusion

It is observed that the cold chain management is satisfactory in the tribal areas of Visakhapatnam, although there are certain gaps and issues such as timely defrosting of cold chain equipment, regular supervision by the in charge officer, monitoring at the outreach site etc. As Visakhapatnam is identified as high risk district, these aspects are to be focused upon to achieve 100% immunization coverage.

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