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ASSESSMENT OF ROUTINE IMMUNIZATION PROGRAMME AT RURAL PRIMARY HEALTH CENTRES IN THOOTHUKUDI HEALTH UNIT DISTRICT, TAMIL NADU, 2023-24

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ABSTRACT

INTRODUCTION: For successful implementation of Routine Immunization (RI) services, all its components such as planning of immunization sessions, cold-chain and logistics management, documentation, monitoring and supervision need to be evaluated from time to time. The objective of this study is to evaluate the process of Routine Immunization in Primary Health Centers in Thoothukudi Health Unit District, Tamil Nadu during April 2023 to March 2024.

METHODS: A descriptive cross-sectional facility-based study was conducted in 14 out of 28 rural PHCs selected by convenience sampling, during April 2023 to March 2024. A checklist adapted from the guidelines in Immunization Handbook for Medical Officers 2018 manual released by Government of India was used.

RESULTS: Of the 14 PHCs, 12 (85.71%) PHCs had the list of estimated beneficiaries, and 13 (92.86%) PHCs had the updated logistics estimation. All the PHCs had their Ice Line Refrigerators (ILR) and Deep Freezers (DFs) with functional thermometers inside. Twice daily recording of temperature in logbook and the supervisory countersign by Medical Officer was observed in all the PHCs. Availability of all vaccines in adequate quantity was observed in only 13 (92.86%) PHCs. **CONCLUSION**: Overall, microplanning, logistics management and supervision were better. Few gaps observed in Cold Chain Equipment (CCE) functioning like inadequate defrosting, not maintaining record of power failure and record of defrosting signal that cold chain handlers have to be periodically be sensitised and reviewed.

KEYWORDS: Routine Immunization, Cold Chain management, Vaccine and logistics

INTRODUCTION

Immunization stands as one of the most costeffective health investments and a major success story for global health and development. Vaccination has consistently proven to reduce morbidity and mortality from numerous infectious diseases, cancers and other chronic diseases, globally. Over the years, various strategies have been implemented globally to ensure that vaccines are available to all individual, including the most hard-to-reach and vulnerable populations to minimize mortality and morbidity. The benefits to the individual include not only the prevention of disease and disabilities but also the opportunity for a healthier and a more productive life.

The World Health Organization (WHO) launched the Expanded Program on Immunization (EPI) in 1974 globally with focus on prevention of six Vaccine Preventable Diseases in children by the year 2000. EPI was introduced in India in 1978, which was expanded in 1985 as Universal Immunization Program (UIP) and implemented in phased manner across all districts in the country by 1989-90. Further, a national socio-demographic goal was set up in National Population policy (NPP) 2000 – to achieve universal immunization of children against all vaccine preventable diseases by 2010. India's UIP is one of the world's

largest health programs and was considered as one of the five 'National Technology Missions' in 1986 bringing it under the scope of the Prime Minister's Office's 20-point program then. The Ministry of Health and Family Welfare (MoHFW), Government of India, launched Mission Indradhanush (MI) in December 2014 as a special drive to vaccinate all unvaccinated and partially vaccinated children under UIP with 7 vaccines, by utilizing the learnings from polio eradication to improve full immunization coverage. This was further expanded as Intensified Mission Indradhanush (IMI) and the recent expansion was IMI 5.0, with a special focus on improving Measles and Rubella vaccination coverage.² Around 1.3 crore Routine immunization (RI) sessions are planned annually in India. Tamil Nadu State started the immunization programme as EPI against six vaccine preventable diseases in 1978. Under the UIP, Tamil Nadu provides 11 Vaccines to around 9.14 lakh newborns and 10 lakh pregnant women against 12 Vaccine Preventable



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Diseases. About 6.75 lakh RI sessions are conducted every year in the State. Dedicated public health staff with their efforts have contributed to a consistent Immunization coverage of over 98% in the State with an average coverage of 1.4 Crores vaccine doses per year. In Tamil Nadu, nine phases of IMI have been conducted since 2015 to 2023 and 2.58 lakh pregnant women and 9.27 lakh children were identified and vaccinated.^{3,4}

Recent years have witnessed developments in Immunization like introduction of new vaccines in National Immunization Schedule, strengthening of VPD surveillance, strengthening of AEFI reporting mechanisms, innovations like eVIN and U-WIN. However, the core and basic functioning like microplanning and implementation of immunisation sessions still remain the cornerstone. Primary Health Centres remain the key player in planning and implementation of the immunisation services.

All the vaccines are sensitive biological products, some being sensitive to freezing, while some are sensitive to heat and others to light. Vaccine potency is ability of the vaccine to adequately protect the vaccinated persons, which can diminish when the vaccine is exposed to inappropriate temperatures. In order to maintain the quality of vaccine products, the process of Cold Chain has to be ensured. Cold Chain is a system of storing and transporting vaccines at recommended temperatures from the point of manufacture to the point of use. PHCs occupy an important position in the cold chain system, with Cold Chain Equipment (CCE) and designated Cold Chain Handlers (CCH).

For successful implementation of routine immunization services, all its components such as planning of immunization sessions, cold-chain and logistics management, documentation, monitoring and supervision need to be evaluated from time to time. Hence, this study is attempted to evaluate the process of Routine Immunization of Primary Health Centers in Thoothukudi HUD, Tamil Nadu during April 2023 to March 2024.

METHODS

A descriptive cross-sectional facility-based study was conducted during April to Aug 2024 in rural PHCs of Thoothukudi Health Unit District (HUD). Thoothukudi HUD has totally seven Block Primary Health Centers, with 28 Rural PHCs and 8 Urban PHCs. Convenience sampling strategy was adopted and two PHCs were selected from each Block. Thus, 14 PHCs out of 28 Rural PHCs were included for the study and were evaluated regarding Routine Immunization Program for the period April 2023 to March

2024.

A checklist adapted from the guidelines in Immunization Handbook for Medical Officers 2018 manual released by Government of India was used for the evaluation. The checklist consists various aspects of Immunization process like program management, cold chain management, injection safety, quality of record keeping, supply and stock etc.

The selected PHCs were visited by District Health Officer (also the designated District Immunization Officer) on Wednesdays which is usually Fixed as Routine Immunization Day. Data was collected by observations of the details in the registers, inspection of equipment and the process. All the data collected was then entered and analyzed using Microsoft Excel. Qualitative variables were presented as proportions.

RESULTS

All the PHCs were evaluated in aspects of immunisation services such as microplanning, Cold Chain management, logistics management and biomedical waste management.

a. Microplanning process of the PHCs: Microplanning is the basis for delivery of Routine Immunization services. Table 1 depicts an overview of the microplanning process in selected PHCs. Availability of complete and updated microplanning is a demonstration of preparedness for delivering quality services. Defining the area and the population covered is displayed as catchment area. For an effective microplanning, availability of catchment area is the crucial indicator as this will guide in fixing the demarcation of population catered by Sub Centers, fixing outreach session sites, estimating the beneficiaries, procuring vaccines and consumables, maintaining buffer stock, etc. Out of the 14 PHCs taken for the study, 13 (92.86%) had the catchment area map prepared.

Estimation of beneficiaries will provide accurate information on the number of children and pregnant women due for vaccination and when to receive vaccines. Of the 14 PHCs, 12 (85.71%) PHCs had the list of estimated beneficiaries. The next component in micro-plan is to estimate the requirement of vaccines and logistics with due consideration of wastage factor. Out of the 14 PHCs, 13 (92.86%) PHCs had the updated logistics estimation. All the 14 PHCs had the session plan. Supervision plan was available in 13 (92.86%) PHCs. Joint review meeting headed by District Immunization Officer (DIO) has been scheduled and conducted as planned in 11 (78.57%) of the PHCs with the Medical Officer (MO), Block Medical Officer (BMO), District Epidemiologist, District Training Team Medical

Officer (DTTMO), District Maternal and Child Health Officer (DMCHO), Sector Health Nurse (SHN), Village Health Nurse (VHN) and Pharmacist every month, which was not conducted in 3 (21.43%) PHCs in one particular month during the study period.

Table 2: Overview of RI Microplanning process of the Rural PHCs,

Thoothukudi HUD, Tamil Nadu, April 2023 to March 2024, N=14

Activities for RI microplanning	n	%
Availability of map of catchment area	13	92.86
Estimation of beneficiaries	12	85.71
Estimation of logistics	13	92.86
Availability of Session Plan	14	100
Availability of Supervision Plan	13	92.86
Joint review meeting conducted in last calendar month	11	78.57

b. Cold chain process: Cold Chain Equipment (CCE), both electrical and non-electrical is used for storing and/ or transporting vaccines at appropriate temperatures. Ice-Lined Refrigerator (ILR) and Deep Freezer (DF) are used to store vaccines and freezing ice packs respectively in PHCs. Ensuring optimal functioning of the cold chain equipment in the recommended standards is critical in ensuring efficacy of the vaccines administered. Table 2 depicts the Cold Chain Equipment functionality/preventive maintenance checklist. ILR/DF should be placed on wooden platform. Of the 14 PHCs, 13 (92.86%) had fulfilled this criterion. Vaccines lose their potency due to exposure to heat (temperature above +8°C), cold (temperature below +2°C) and light, hence ILR temperature to be maintained between +2°C to +8°C, which was fulfilled by all the selected PHCs. Temperature of DF to be maintained between -15°C to -25°C, which was fulfilled by 12 (85.71%) PHCs. Icepacks has to be arranged vertically in a crisscross pattern with space for air circulation in DF, which was observed in 12 (85.71%) PHCs. Thickness of the frost formation should not be more than 5 mm in ILR and DF. All the PHCs had this criterion fulfilled in ILRs, but in DF, only 11 (78.57%) PHCs had maintained this condition.

All the vaccine vials to be arranged in the ILR based on the heat or freeze sensitivity. The T series/Hepatitis B vaccines which should be placed in the top of the ILR and the correct placement of all vaccines, fulfilled in all the PHCs. Record of the power failure to be maintained at PHCs, which was maintained at only 4 (28.57%) of the PHCs. All the PHCs had their ILR and DFs with functional thermometers inside. Twice daily recording of temperature in logbook and the supervisory countersign by Medical Officer was observed in all the PHCs.

Table 3: Checklist for preventive maintenance of ILR/DF at Rural PHCs,

Thoothukudi HUD, Tamil Nadu, April 2023 to March 2024, N=14

S. No	Checklist	n	%
	External		
1	ILR & DF placed on wooden stand	13	92.86
2	ILR & DF placed 10cm away from the wall	14	100
	Internal		
1	ILR Temperature between +2°C to +8°C	14	100
2	DF Temperature -15°C to -25°C	12	85.71
3	Correct placement of Ice packs inside DF	12	85.71
4	All vaccine vials arranged correctly (heat/freeze sensitivity) inside ILR	14	100
5	All vaccine vials placed inside labeled cartons	12	85.71
6	No T series and Hepatitis B vial placed at the bottom of ILR	14	100
7	Diluents placed inside ILR at least 24 hours before distribution	14	100
8	Thickness of frost formation not more than 5 mm inside ILR	14	100
9	Thickness of frost formation not more than 5 mm inside DF	11	78.57
	Technical		
1	Connected through functional voltage stabilizer	14	100
2	Functional thermometer inside ILR	14	100
3	Functional thermometer inside DF	14	100
4	Twice daily recording of temperature in log book	14	100
5	Record of power failure	4	28.57
6	Record of defrosting	13	92.86
7	Signature of MO in temperature log book	14	100

c. Logistics management of immunization in PHCs:

Availability of vaccines in adequate quantity is the primary requirement for conducting immunization sessions. During the visit, adequate stock was observed in 13 (92.86%) PHCs. Inadequate stock of IPV vaccine was observed in one PHC during the study period. However, timely monitoring was done through eVIN and vaccines supplied adequately. This is reflected through the issue of all vaccines for each session from all PHCs. Stock register to be updated at the end of each session, which was lacking in 2 PHCs (14.29%). Discrepancy between the stock in eVIN and the actual stock was observed in 1 PHC (7.14%), as stock was not updated in eVIN. Record of diluents was updated in all PHCs, however the record of Auto Disabled syringes was updated in 13 (92.86%) PHCs (Table 3).

Table 4: Logistics management of immunization at Rural PHCs,

Thoothukudi HUD, Tamil Nadu, April 2023 to March 2024, N=14

S.No	Components		%	%	
1	All vaccines available at adequate quantity		13	92.86	
2	Stock Register updated		12	85.71	
3	Data discrepancy observed in stock		1	7.14	
4	All vaccines issued for each session from PHC		14	100	
5	Record of Auto Disabled syringes updated		13	92.86	
6	Record of diluents updated		14	100	

d. Steps to ensure safe disposal of biomedical waste:

Immunisation wastes include sharps like used needles and broken vials, non-sharps like used syringes without needles and unbroken vaccine vials and general wastes packaging and swabs. The Central Pollution Control Board (CPCB) has outlined the guidelines for safe disposal of biomedical wastes generated during immunization under the Universal Immunization Programme. All biomedical wastes to be segregated in colour coded bins and biomedical waste collection register to be maintained in all PHCs. This was observed in all PHCs.

Overall, the PHCs had performed fairly aligned with the guidelines. Microplanning aspects and biomedical waste handling were better. Certain gaps in CCE like not placing ILR and DF on wooden platform, not maintaining the recommended temperature in DF, not defrosting the DF periodically, not maintaining record of power failure and record of defrosting. With timely monitoring, the stocks are adequately supplied, but documenting of stock status needs to be improved.

DISCUSSION

This study evaluates the immunisation programme of PHCs. For efficient functioning of the RI programme, certain key responsibilities are designated to the DIOs and MOs such as planning and reviewing, implementation, maintaining beneficiary line list at PHC/ Block level, Supervision and Monitoring, Cold chain and logistics management and monitor tracking of new-borns and dropouts.¹

The major activities to be fulfilled by PHCs are: availability of map of PHC showing the SC/ANM area demarcation, Compiled RI micro-plans from all SC/ANM area, Supervision plan, Cold Chain contingency plan, Immunization waste disposal plan and ANM work/roster plan1. A good micro-plan ensures that a) all boundaries of the catchment area are identified, b) all health workers are aware and have line list of their catchment areas and that no villages/urban area or high-risk population pockets or unserved areas have been left out, c) all beneficiaries have been identified and information is available on who has to

be vaccinated and with which antigen d) Adequate planning of sessions as per injection load for all identified areas using fixed/ outreach/ mobile sessions is done e) ANM roster is developed.¹

Availability of map depicting catchment area was available in 13 (92.86%) PHCs, which has to be updated in the remaining PHC as this is the first step in microplanning. Conducting head count survey is an important step in RI microplanning process, which will ensure enrollment of all beneficiaries in an area.

Thus, having an estimation of beneficiaries is an indirect way of evaluating the process of head count survey. Estimation of beneficiaries is the basis for calculating the required vaccines, what vaccines and when to be vaccinated. However, this was available in only 12 (85.71%) PHCs and lacking in 2 PHCs. Regarding logistics, 12 (85.71%) PHCs had estimated the required logistics in terms of vaccines, auto disabled syringes, etc. All the selected PHCs had the session plan, in line with the recommended guidelines.

The CCE in PHC are ILR, DF, vaccine carrier and cold box. In the present study, ILR/DF were assessed. ILR/DF should be placed on wooden platform and their positioning should be 10 cm away from the wall. Of the 14 PHCs, 13 (92.86%) PHCs had fulfilled the criterion of placing ILR/DF over the wooden platform and all the PHCs had placed the ILR/DF 10 cm away from the wall.

Frozen icepacks are to be stored only up to half of the height of large compartment in the DF, unfrozen ice packs to be placed above the frozen ice packs. About 20 to 25 dry and unfrozen icepacks has to be arranged vertically in a crisscross pattern with space for air circulation.

In the present study, 12 (85.71%) PHCs had placed the Ice packs as recommended in DF, while Pradeep et al5 had reported that only 66% had fulfilled this criterion. Patel N6 had reported that crisscross ice packs arrangement was present in 76.7% of total ILRs. As per the recommendation, T series/Hepatitis B vaccines should be placed in the top of the ILR, which is fulfilled in all the PHCs.

Vaccine diluents should be stored in the ILR. The diluents may be stored outside the cold chain if there are space constraints in ILR. However, diluents must be kept in ILR at least 24 hours before use or issuing to sessions to ensure that vaccines and diluents are at same temperature (i.e., $+2^{\circ}$ C to $+8^{\circ}$ C) during reconstitution, to thermal shock that is, the death of some or all the essential live organisms in the vaccine. All the PHCs had fulfilled this criterion.

Every CCE (ILR and DF) must be connected to an individual functional voltage stabilizer. The function of

the voltage stabilizer is to monitor and stabilize the range of fluctuations in the main incoming voltage to safeguard equipment from excessive voltage variation.

Voltage stabilizers prevent excessive voltage variation, providing specified constant stabilized voltage to CCEs (ILRs & DFs) for its desired optimum operation and to protect vaccines. Bypassing a voltage stabilizer can damage the CCE. In the present study, all the PHCs had the CCEs connected to functional voltage stabilizer.

Alcohol stem thermometers are very sensitive and more accurate than dial thermometers. This is the most commonly used temperature monitoring device under UIP. Each CCE should contain at least one functional thermometer and should always be placed along with the vaccines. Twicedaily readings from the stem thermometer must be entered in the individual temperature logbooks on all days including Sundays and holidays. Temperature logbooks have to be reviewed by Medical Officer (MO) every day. In the present study, all the PHCs had fulfilled the three criteria- functional thermometer in ILR, functional thermometer in DF and twice daily recording of temperature in logbook, signed by MO. However, there were certain gaps observed in CCE like not placing ILR/DF on wooden platform, not maintaining the recommended temperature in DF, not defrosting the DF periodically, not maintaining record of power failure and record of defrosting. However, most of these issues were in DF and not in ILR. These deficiencies signal that cold chain handlers have to be periodically sensitised and reviewed.

At the PHC level, the requirement of vaccines and logistics has to be estimated compiling the micro plan of all the Health Sub-Centres (HSCs) and considering the buffer stock and wastage rates. Availability of all vaccines in adequate quantity was observed in only 13 (92.86%) PHCs.

However, this inadequacy in vaccine stock is because of the higher number of doses per vial in IPV, leading to increased wastage and early stock out. But this is timely monitored through eVIN and supplies ensured adequately. All the required vaccines for immunisation sessions were issued by all PHCs. Digital innovation and upgradation through eVIN have facilitated adequate vaccines stock supply and availability.

CONCLUSION

The present study has provided meaningful insights on the completeness and gaps of RI services in PHCs.

Components of microplanning of Immunization services aligns with guidelines recommended. Biomedical waste disposal was also done according to the set standards. The gaps observed in CCE functioning like inadequate defrosting, not maintaining record of power failure and record of defrosting signal that, cold chain handlers have to be periodically sensitised and reviewed. Logistics management like not updating stock registers need to be closely monitored. This study has also reiterated the role of digital technologies in monitoring and ensuring timely availability of vaccines stock.

DECLARATION OF INTEREST

The authors declare no conflict of interest

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