

Original Research Article

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## Uptake of fIPV3 and implementation challenges as perceived by auxiliary nurse midwives at two primary healthcare centers in urban Bengaluru: a mixed-method study

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### ABSTRACT

**Background:** India introduced fractional-dose inactivated poliovirus vaccine (fIPV) into its routine immunization program as part of the polio eradication and endgame strategic plan. The study aimed to assess the uptake of the 3rd dose of fIPV among eligible beneficiaries and explore the implementation challenges perceived by auxiliary nurse midwives (ANMs) at two primary healthcare centers in urban Bengaluru.

**Methods:** A mixed-method study was conducted between April and May 2023. A cross-sectional design was used for quantitative objectives, while in-depth interviews were conducted with ANMs for qualitative insights. Data were collected through vaccination registers, questionnaires, and key informant interviews. The study population included all eligible beneficiaries for the 3rd dose of fIPV from January to March 2023.

**Results:** Out of 296 eligible beneficiaries, 139 (47%) had received the 3rd dose of fIPV. The challenges faced by ANMs in fIPV3 implementation included difficulties in recording and reporting activities, fear of managing adverse events, lack of confidence in administering intradermal injections, obtaining consent from parents, inadequate training, and concerns about vaccine wastage and increased workload.

**Conclusions:** The uptake of fIPV3 was suboptimal, and ANMs encountered several challenges during implementation. To enhance fIPV3 integration into the vaccination schedule, the health system needs to improve awareness among the community, strengthen health worker capacity, and provide better training and support. Strengthening routine immunization programs can contribute to sustained polio eradication efforts.

**Keywords:** Fractional-dose inactivated poliovirus vaccine, Implementation challenges, Auxiliary nurse midwives, Routine immunization, Polio eradication, Urban Bengaluru

### INTRODUCTION

Globally, the World Health Organization (WHO) declared the completion of polio eradication, a programmatic emergency for global public health.<sup>1</sup> India was certified polio-free along with 10 other countries of the WHO South-East Asia Region on 27 March 2014 and has maintained its polio-free status for over 5 years now.<sup>2</sup>

In India around 85% of polio immunization coverage among one-year children is seen in 2021.<sup>3</sup> However, India is still at risk of wild poliovirus importation from areas where transmission is still ongoing.<sup>4,5</sup> The country also possesses the risk of vaccine-associated paralytic polio (VAPP) cases and the emergence of vaccine-derived polioviruses (VDPVs).<sup>6</sup> Polio (poliomyelitis) mainly affects children under 5 years of age, with 1 in 200

infections leading to irreversible paralysis. Among those paralyzed, nearly 5% die when their breathing muscles become immobilized. Thus, polio eradication and endgame strategic plans were developed in which they suggested the countries to have at least one dose of inactivated poliomyelitis vaccine (IPV) in the routine immunization program. The addition of IPV provides an immunity base to reduce the risk of polio disease in case of any exposure to the type 2 poliovirus following the switch from trivalent to bivalent oral polio vaccine (tOPV2 to bOPV2).<sup>1</sup>

India was the first country to introduce fractional-dose inactivated poliovirus vaccine (fIPV) into routine immunization, initially in eight states in 2016. Following a rapid assessment of its initial implementation, fractional dosing was extended and, by June 2017, all Indian states were covered. The fractional dose of IPV is a smaller dose of the same vaccine equal to one-fifth of a standard dose. As per the directions of the government of India (GoI), the government of Karnataka has introduced fIPV in routine immunization from 1st January 2023 onwards. The schedule for fIPV is in the 6th week, 14th week, and 9th month along with Pentavalent, oral polio vaccine (OPV), Rotavirus Vaccine (RVV), and Pneumococcal Conjugate Vaccine (PCV) while fIPV3 is given along with the Measles vaccine in the 9th month.<sup>7</sup> The route of administration is intradermal with a dose of 0.1ml using a Bacillus Calmette Guerin (BCG) syringe.<sup>8</sup> The route of administration for the third dose will remain the same (intradermal) and the site of administration will be at the left upper arm as the Measles and rubella (MR) vaccine will be given on the right arm.<sup>9</sup> The site of vaccination is on the right upper arm during the 6th and 14th week and the left upper arm during the 9th month.

Vaccines are important as Polio can paralyze children but it can be prevented through vaccination. In addition to polio, vaccines can protect from other very serious and sometimes deadly diseases. As the uses of fractional-dose inactivated poliovirus vaccine is dose-sparing and reducing the cost of the immunization program, it will remain an important part of India's long-term strategy for polio vaccination.<sup>10</sup> Any newer public health initiative encounters challenges during implementation. After talking to the program managers and subject experts, we were convinced that the implementation challenges lie during the administration of the fIPV3 dose as the administration of two injectable vaccines is new to the health workers and the beneficiaries. We anticipate that the trends of uptake of the fIPV dose might increase steadily over a period of time and also the health workers in the field might experience enormous challenges in the implementation of this initiative. Hence, we conducted a study to determine the uptake of 3rd dose of fIPV among the eligible beneficiaries (9-12 months) and also to describe the implementation challenges faced by auxiliary nurse midwives (ANM) in administering 3rd dose of fIPV

at selected two Primary Healthcare Centers (PHC) at Bengaluru city.

## METHODS

### *Study design and setting*

A community-based mixed-method study was conducted between April and May 2023. A cross-sectional study design was used to study the quantitative objectives while we conducted in-depth interviews of participants to understand the challenges faced by them. Ethical clearance was taken from the institutional ethics committee and carried out in the field practice area of the two Urban Health and Training Centers (UHTC), centers of ESIC Medical College and PGIMSR, Bengaluru. The two Primary Healthcare Centers cater to a general population of nearly one lakh and are equipped with the necessary infrastructure and human resources. The two Primary Healthcare Centers have seven subcenters together and they perform outreach activities of immunization every Thursday at a designated place in their respective areas. Each outreach activity lasts for about 2 to 3 hours and the Accredited Social Health Activist (ASHA) workers mobilize the children from each house who are due for the vaccination. Nearly 50 vaccine doses are provided to the children every week. All the details of children vaccinated are recorded manually in a register as well as the immunization card of the beneficiaries.

### *Study population*

All the eligible beneficiaries for the 3rd dose of fIPV (9-12 months) from the period 1st January 2023 to 31st March 2023 were included in the study.

### *Sample size calculation*

The sample size for the uptake of 3rd dose of fIPV among the eligible beneficiaries was estimated using a formula for a single proportion with adjustment for clustering. The sample size was calculated using [www.openepi.com](http://www.openepi.com) which is freely available online software for sample size calculation. We assumed a 95 percent level of confidence, a 10 percent sampling error proportion of eligible children receiving fIPV3 as 50 percent, and a design effect of one. This gave an estimated size of 193. The adjustment rate for non-response was presumed to be 10 percent and it yielded a sample size of 212.

### *Sampling technique*

The number of beneficiaries in each sub-center of the Primary Healthcare Centre was calculated using the population proportion to sample size (PPS) technique for each subcentre. The list of eligible beneficiaries for fIPV3 was obtained from the vaccination registries maintained at the subcenter by the ANM. Convenient sampling was made to select the ANM for key informant interviews.

### **Inclusion and exclusion criteria**

All the eligible beneficiaries for the 3rd dose of fIPV (9-12 months) as per the vaccination registers maintained from the period 1st January 2023 to 31st March 2023 were included in the study.

### **Data variables**

We collected the information of children vaccinated at each center through vaccination registers at sub-centers and the general information about the PHC from the registers maintained at PHC. The dependent variables of fIPV3 uptake are the number of eligible beneficiaries who have been vaccinated to fIPV3. The independent variables are the availability of the fIPV3 vaccine at the sub-center and the related factors and the implementation challenging factors for auxiliary nurse midwives.

### **Data collection process**

The key informants (Auxiliary Nurse Midwives) were purposively selected and interviewed by trained personnel at a place and time convenient to them using a standardized key informant interview guide in their local language. Each interview lasted for about 15 minutes and written informed consent was taken before the interview. A semi-structured questionnaire was used to collect the data and it has four parts. The first part consisted of general information or profiles of Primary Healthcare Centers. The second part included the details of the beneficiaries and the activities performed to immunize the children in the vicinity. The third part included the status of fIPV3 implementation in PHC. The fourth part included the challenges faced by auxiliary nurse midwives for fIPV3 implementation. The key informant interviews were conducted with the help of a qualified social researcher using a KII interview guide in the

presence of the principal investigator and in a conducive space within the facility at a time convenient to them and audio recorded.

### **Data analysis**

Data were entered using Microsoft Excel 2013 and analyzed using freely available data analysis software EpiData 3.1 (Odense, Denmark) Analysis Software. The completeness and correctness of data were checked at the point of data collection. The magnitude was expressed in percentage along with its 95% confidence interval (CI). Categorical variables were presented as proportions (%). The qualitative data was analyzed using content analysis through transcription, and coding, and then arranged the findings into major topics.

### **Ethics**

The ethics approval was obtained from the ethics community of ESIC Medical College and PGIMSR, Bengaluru. Informed consent was obtained from the subjects participating in the study. The participants were given a unique ID instead of names to ensure the confidentiality of the participants.

## **RESULTS**

Among the 296 eligible beneficiaries, 139 (47%) had received fIPV3, while the remaining were yet to receive the vaccine (Table 1). There were seven subcenters in these two PHCs with an average population coverage of 15,000. All the subcenters conducted vaccination every Thursday and one outreach activity once a week. With regards to the fIPV3 implementation, there were adequate logistics which included the availability of BCG syringes, vaccine carriers, and ice packs, and an efficient microplan was available for all subcenters.

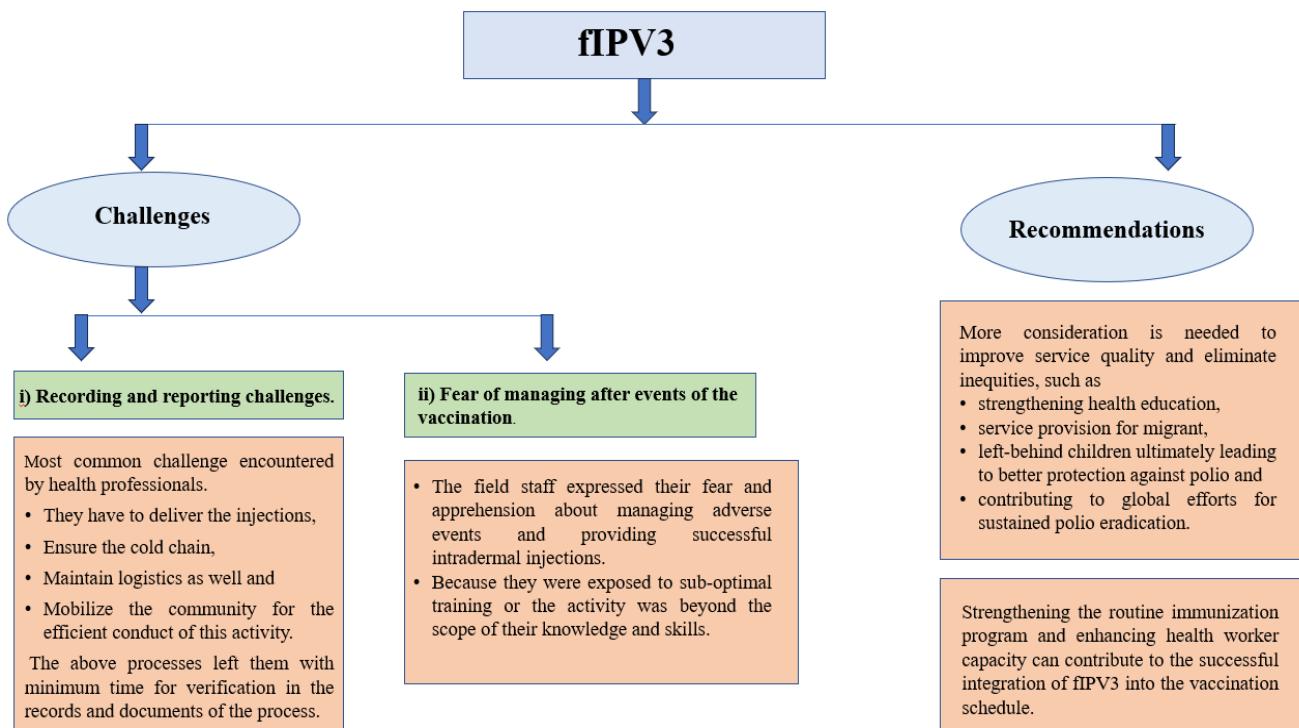
**Table 1: Distribution of details on activities and challenges faced by ANM for fIPV3 implementation.**

S. no.	Challenges faced (n=7)	Yes (%)
1.	Recording and reporting on the activity	6 (85)
2.	Fear of minor or major adverse events	3 (42.8)
3.	Disposal of used syringes	2 (28.5)
4.	Apprehension with regard to Intradermal injections	2 (28.5)
5.	Counseling of eligible child's parents	1 (14.2)
6.	Training component	1 (14.2)
7.	Fear of vaccine wastage	1 (14.2)
8.	The addition of fIPV3 considered a burden to their routine activity	1 (14.2)

**Table 2: Distribution of fIPV3 vaccine coverage across the PHCs.**

PHC	fIPV 3 received		Total (%)	P value
	Yes (%)	No (%)		
PHC 1	79 (55.3)	64 (44.7)	143 (48.3)	
PHC 2	60 (39.3)	93 (60.7)	153 (51.7)	*0.005
<b>Total</b>	<b>139 (47)</b>	<b>157 (53)</b>	<b>296 (100)</b>	

p value <0.05 =statistically significant.



**Figure 1: Challenges and recommendations in view of fIPV3 administration.**

We came across several challenges for fIPV3 implementation as perceived by the ANMs (Table 2, Figure 1). Firstly, the majority of them (85%) considered recording and reporting the activity as a major challenge for implementation. Secondly, fear of minor or major adverse events after vaccination at the vaccination site was perceived to be challenging as they were ill-prepared to handle the situation. Thirdly, the field staff were apprehensive about giving intra-dermal (ID) injections as they were not confident in understanding whether the given injection was appropriate or not. Fourthly, a few of the field staff found it difficult to obtain consent from the parents of the beneficiaries for these new vaccines as many of them were not aware of the induction of the vaccines under the immunization schedule. Fifthly, the vaccinators also felt that the training given to them was suboptimal and they also feared wastage of vaccine doses would instigate disciplinary action against them. Some of them also felt that the addition of this newer vaccine burdens their routine activity.

## DISCUSSION

Our study findings revealed that the fIPV3 uptake was seen in one in two beneficiaries. We also noticed several challenges by the field staff for fIPV3 implementation.

### Recording and reporting challenges

This is the most common challenge encountered by health professionals as they have to deliver the injections, ensure

the cold chain, maintain logistics as well and mobilize the community for the efficient conduct of this activity.

The above processes left them with minimum time for verification in the records and documents of the process. However, these challenges can be mitigated if the health system is equipped with an efficient electronic-based mobile reporting mechanism.

### Fear of managing after events of the vaccination

The field staff expressed their fear and apprehension about managing adverse events and providing successful intradermal injections probably because they were exposed to sub-optimal training or the activity was beyond the scope of their knowledge and skills.

The program has to build the capacity of the vaccinators by providing them with good quality e-modules for training and assisting them with 24/7 helplines to interact with the physician and provide remedial actions.

### Limitations

The study's limitations include its cross-sectional nature, which limits causal inferences, and the focus on two primary healthcare centers, which might not represent the broader urban Bengaluru population. Additionally, the study did not explore the reasons for low vaccine uptake or specific strategies to overcome the identified challenges.

## CONCLUSION

The uptake of fIPV3 was suboptimal and several challenges were faced by the implementing health care workers. The health system has to strengthen the awareness of the fIPV3 among the community and also build the capacity of the health care workers and program managers for prompt implementation of the activity.

### Recommendations

Strengthening the routine immunization program and enhancing health worker capacity can contribute to the successful integration of fIPV3 into the vaccination schedule. More consideration is needed to improve service quality and eliminate inequities, such as strengthening health education and service provision for migrant and left-behind children ultimately leading to better protection against polio and contributing to global efforts for sustained polio eradication.

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*Ethical approval: The study was approved by the Institutional Ethics Committee*

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