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## RESEARCH ARTICLE

# A SOCIODEMOGRAPHIC STUDY TO EVALUATE THE PATTERN OF ADVERSE DRUG REACTION WITH NEW INACTIVE OR INJECTABLE POLIO VACCINE AND AWARENESS ABOUT IPV

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### ABSTRACT

The introduction of one dose of IPV into routine immunization programme is to mitigate risks associated with OPV withdrawal and potential reintroduction of poliovirus. In polio Eradication and End Game Strategic Plan, SAGE (Strategic Advisory Group Of Experts) on Immunization has recommended that all OPV using countries should introduce one dose of IPV into routine immunization schedule and administer that dose at or >14 weeks of age in addition to the 3 to 4 doses of OPV in primary series. India has incorporated IPV under National Immunization Programme in November 2015. Our study focused on awareness about IPV among people and health care workers. We carried out this study to collect sociodemographic profile for monitoring use, and coverage of IPV, to identify the pattern of adverse drug effects with new IPV, to assess the knowledge and awareness about IPV in society. Though our study showed that with 97.7 to 100 % coverage of immunization with IPV, only minor local complaints after IPV administration but no single adverse events reported or documented either by the parent or by the health care persons. Our study information is useful to find how effectively immunization targets have met and -how efficiently the IPV is being used. Detected adverse drug reactions with IPV would be helpful -to maintain Universal Immunization Programme. This pilot project was undertaken with provision of use of IPV in routine and campaigns to assess vaccine acceptance to support country policy decisions; and ecologic studies in developing countries switching to all-IPV routine immunization schedules to evaluate potential emergence of cVDPVs and risk of WPV importations.

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## INTRODUCTION

The primary role of introducing one dose of IPV into routine immunization programme is to mitigate risks associated with OPV withdrawal and potential reintroduction of poliovirus. (Meeting of the strategic Advisory Group of Experts on Immunization, 2013) In polio Eradication and End Game Strategic Plan, SAGE (Strategic Advisory Group Of Experts) on Immunization has recommended that all OPV using countries should introduce one dose of IPV into routine immunization schedule and administer that dose at or >14 weeks of age in addition to the 3 to 4 doses of OPV in primary series (Meeting of the strategic Advisory Group of Experts on Immunization, 2013; Societe des Nations, 2014; Meeting of the strategic Advisory Group of Experts on Immunization, 2012).

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IPV is completely safer vaccine and not such serious adverse drug reactions are reported. The main advantage over the OPV is that it induces immunity against type II poliovirus, boost the intestinal immunity and prevent the paralysis. (Meeting of the strategic Advisory Group of Experts on Immunization, 2013; Moriniere et al., 1993; Estivariz et al., 2012; Faden, 1991; Faden et al., 1990). Apart from this when IPV is given along with OPV results in additive immunity. (Estivariz et al., 2012; Faden, 1991) India has incorporated IPV under National Immunization Programme in November 2015. Our study focused on awareness about IPV among people and health care workers. Our study information is useful to find how effectively immunization targets have met and -how efficiently the IPV is being used. Detected adverse drug reactions with IPV would be helpful -to maintain Universal Immunization Programme. We carried out this study to collect sociodemographic profile for monitoring use, and coverage of IPV, to identify the pattern of adverse drug effects with new

IPV, to assess the knowledge and awareness about IPV in society.

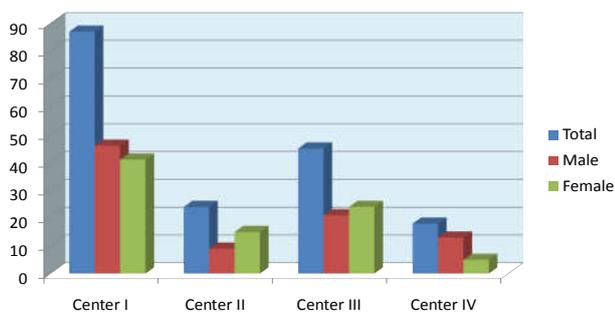
## MATERIALS AND METHODS

This multicenter, non-comparative, non interventional, observational, prospective study was conducted at Dr. D.Y. Patil Medical College and Research Institute, Kolhapur. Data was collected from Immunization centers under Dr. D.Y. Patil Hospital and research institute, Kolhapur. Infants ranging from 5 weeks to 1 year of age registered for immunization are included in this study. The study was carried out in April 2016 to September 2016 for the period of 6 months and those beneficiaries enrolled during this period are incorporated in this study. Study was conducted after approval of institutional ethical committee and Informed consent of any one parent or associated person with the baby was taken before hand. A self prepared information data sheet and feedback questionnaire from beneficiaries and health workers was used for collecting information. The data was assessed and analyzed in terms of percentage.

**Table 1. Age wise distribution of immunization status in Children**

No. & CENTER	Total No. of Immunization	At 4 weeks & above (1st dose of IPV)		At 10 weeks & above (IInd dose of IPV)	
		No	%	No	%
Center I	87	87	100	87	100
Center II	45	45	100	43	95.5
Center III	24	24	100	22	91.6
Center IV	18	18	100	18	100
Total	174	174	100	170	97.7

**Graph 1: Base Line Data showing sex wise distribution of immunization status in Children**



## RESULTS

### General characteristics of the study beneficiaries and participants

Majority of the beneficiaries involved in our study (90.15%) were aged between 4 to 10 weeks. Females were less or equal (49.43 %) than the males (50.57 %) (Graph 1). Parents who had attained at least a Primary School education were 4.2%, 16.2 % completed. Secondary School Education and 79.6% attained college or University. Surprisingly all the parents were aware about Polio immunization but very few 12% were having knowledge about IPV, its schedule and vaccination details. Remaining 88% are ready to immunize baby when they were acknowledged about IPV. Majority 88.2% of the parent had only 1 child while 11.8% had 2

children. 98.3% of children were aged between 4 weeks to 10 weeks and only 1.7% only above mentioned age. 97.5% of the children were born by hospital deliveries and only 0.1% through Traditional birth attendants. The study showed that 174 (100%) of the children were immunized with first dose and 170 (97.7%) with second dose of IPV by history. The immunization coverage of IPV was therefore outstanding with the dropout rate between the first and second dose of IPV was 2.8%. (Table 1)

### Adverse events after IPV administration

Our study data showed 25 % of children had mild local adverse events and 2% moderate but no severe (0%) adverse events (Table 2).

**Table 2. Adverse events after IPV administration**

Adverse events	Severity			
	Mild No (%)	Moderate No (%)	Severe No (%)	
Local	Pain	35 (20)	18 (10)	1
	Swelling	4 (2)	4 (2)	--
	Redness	4 (2)	4 (2)	--
	Itching	25 (15)	4 (2)	--
	Abscess	4 (2)	4 (2)	--
Systemic	Fever	18 (10)	--	--
	Irritation	25 (15)	--	--
	Seizures	--	--	--
	vommiting	--	--	--

### Awareness in Health workers about IPV

Our study found out that all health workers are well trained for IPV administration and aware about importance of immunization as well as its eradication. All health workers are aware about adverse events that might occur after administration. All beneficiaries are well informed with IPV immunization by health workers.

## DISCUSSION

This study in four different immunization centers represents the small survey about IPV administration with sociodemographic profile. The survey was strengthened by the study about awareness of IPV in health workers as well as in society. Some studies shown that Social barriers like gender, caste, pardah system, etc. have always limited the administration of pulse polio vaccine as there is poor vaccine acceptance by certain religious groups in states like Bihar and UP. There are still various myths present in the community like children becoming sterile after taking polio drops and a large conspiracy by USA to finish a certain community. (WHO, 2012; John, 2004) But in our study beyond this results are obtained like female children are vaccinated less or equal (49.43 %) to the male children (50.57 %). No any defiance was reported in any case and resistance is almost negligible. No any caste variables, education or income status of the parents showed difference in immunization task. As we know Global polio eradication initiative envisages a need community participation to maintain momentum at global, national, and regional level. It also emphasized the importance of strengthening routine immunization to prevent reemergence and/or re importation of the wild polio virus. (Myths still keep families away from Polio drops, 2010; John and Vashishtha, 2009) Our study data strengthens this showing total 174 (100%) of the children were immunized with first dose and 170 (97.7%) with second dose

of IPV. The immunization coverage of IPV was therefore outstanding with the dropout rate between the first and second dose of IPV was 2.8% may be because of shifting of beneficiaries to different place or any medical ill health. Though our study showed that with 97.7 to 100 % coverage of immunization with IPV, only minor local complaints after IPV administration but no single adverse events reported or documented either by the parent or by the health care persons. There is always a debate that whether polio cases in India are occurring because of vaccine failure or due to failure to vaccinate. While Indian official figures claim 90% coverage but a survey done by WHO and UNICEF during the same period shows coverage to be only 20-40% (Majiyagbe, 2004). Some viewpoints before including IPV in routine immunization programme are like weather this task leading to fatigue and demotivation of the healthcare staff to take concrete efforts (Lahariya, 2007). But in our survey we found that all health workers are involved in this programme with well trained hands and all information and knowledge about IPV. IPV requires a large number of trained human resources (health workers) for its administration in the general population (Lahariya, 2007). All centers in our study are having adequate trained staff. Besides this we observed that there is provision of sterile syringes, appropriate disposal of the used syringes and needles, observing universal precautions by healthcare personnel, etc. We also observed that health workers are informing beneficiaries about new IPV vaccine its route, dose, precautions to be taken and likely adverse events after administration of vaccine. Health workers are sincerely taking efforts during preliminary work to aware beneficiaries about importance of water, hygiene, and sanitation and effectiveness of IPV. Also techno-centric approach of health workers regarding cold chain maintenance, record maintenance, community awareness and implementation of new strategies is strengthening this global programme.

### Conclusion

Our communities by overcoming their myths and misbelieve just by involvement in polio immunization supporting Global Eradication Programme. Understanding the fact that polio eradication is for the own need and not just as a government duty inculcating in them. Besides conventional strategies like routine high immunization, NIDs, surveillance of AFP, and mopping up vaccination, newer strategies like special supplementary immunization activities are going on in underserved, hard to reach areas, and transit points (bus stops, railway stations) for Oral Polio Vaccination. But during feedback collection, we observed that no such strategies are planned for IPV. This may be because of recent incorporation of IPV in routine immunization Schedule. Although the cost of manufacturing IPV and OPV is same, IPV's high demand in industrialized nations and consequent low supply makes it 10 times costlier. This may affect constant vaccine supply by government and restricts its maintenance in routine immunization programme. Mild adverse events observed with IPV administration could be either due to IPV or Pentavalent vaccine as in India IPV is given in combination with Pentavalent. The combined efforts of Health care workers and aids from Government of India with WHO and coordination by National Polio Surveillance Project, polio eradication program in India is on the way to achieve goal. Eradication efforts started without, impact of sustained, and prolonged eradication drive on routine immunization, and issues concerning the goal

of eradication itself. An effort has been made to discuss the socioeconomic and public health importance.

### Summary and Implications

- Our study showed the IPV immunization awareness in society i.e both in parents and health care persons. This knowledge of social awareness of IPV will be helpful in the programme like National Immunization Programme.
- Our Study data showed that 97.7% of children are immunized with IPV. This shows that 100% awareness and no social barriers limiting immunization programme.
- In our study 25% children showed mild and 2% children showed moderate but none of the severe adverse event noted in immunized child with IPV. This study based project will give pattern of adverse drug reaction on specific pediatric age group.

Our study data will be helpful to create an infrastructural pattern to study the use and coverage of IPV.

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