Final Technical Report

for

Research Project

‘Cross-Sectional Serologic Assessment of Immunity toPolioviruses and Measles-Rubella in Different Risk States of India

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Final Technical Report

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India Polio /MR Seroprevalence Study: 2024

Study Completion Report

Study title

‘Cross-Sectional Serologic Assessment of Immunity to Polioviruses and Measles-Rubella in Different Risk States of India.’ (India Seroprevalence Study - 2024)

Collaborating Institutions

Indian Council of Medical Research (ICMR)

Ministry of Health & Family Welfare, Government of India

World Health Organization, India

Government of Assam

Government of Maharashtra

Government of Rajasthan

Government of Uttar Pradesh

Designated State Medical Colleges & Labs

NielsenIQ (India) Private Limited

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1.0 Study Background

Since the launch of the Global Polio Eradication Initiative (GPEI) in 1988, five of the six World Health Organization (WHO) regions have been certified wild poliovirus free. The last case of WPV2 was detected in 1999 and last WPV3 was detected in 2012. There are only two endemic countries for type 1 wild poliovirus (WPV1) – Afghanistan and Pakistan. The GPEI Endgame Strategic Plan (2022-2026) outlined to strengthen plans to achieve and sustain polio-free world with the main focus to cut outbreak response time, increasing vaccine demand, transforming campaign effectiveness, increasing access to vaccines In inaccessible areas, and transitioning towards government ownership. The first milestone of the Endgame Strategic Plan was a globally synchronized switch from tOPV to bivalent OPV (bOPV containing types 1 and 3 Sabin poliovirus), which was implemented in April 2016, with the withdrawal of type 2 component from the immunization program. To mitigate the risk of type 2 immunity, IPV was gradually introduced in routine immunization (RI) at or after 14 weeks of age in all OPV-using countries. Adding IPV to bOPV schedule could supplement the immunity for types 1 and 3, while providing a good type 2 baseline immunity to guard against cVDPV2.

India contributed to over 60% of all global polio cases until 2009. The country was certified polio free in 2014, since the last case was reported in 2011. However, India's neighbouring countries, Afghanistan and Pakistan, continue to report circulation of WPV1. Therefore, it is essential to maintain very high population immunity through continued polio vaccination in India, that will reduce the risk of cVDPVs as well. The EPI schedule in India includes 5 doses of bOPV at birth, 6, 10 and 14 weeks and a booster dose at 16-24 months combined with 3 fractional IPV doses. IPV introduction in India moved through serial changes, first one full dose at 14 weeks, then two fractional doses at 6 and 14 weeks and with the latest revision, three fractional doses of IPV at 6, 14 weeks and 9 months [R]. Post tOPV-bOPV switch, type-2 immunity is expected to be dependent on IPV, as bOPV aims to provide immunity against types 1 & 3 only.

To mitigate the risks associated with WPV importations and emergence of cVDPVs, India continues its efforts to raise population immunity through mass vaccinations and improvements in routine immunization coverage. India conducted regular serosurveys during 2007-2019 to assess the population immunity against polioviruses in the high-risk areas. These serosurveys indicate that India attained high seroprevalence by the year 2011; the year the last WPV case was reported in India. These high levels of seroprevalence were sustained in the subsequent years. The latest polio seroprevalence study in India was conducted in 2019 in the high-risk states UP (traditional high risk), Assam (low routine Immunization coverage), Telangana (state with low surveillance Index) and Delhi (State with latest VDPV in environmental samples). The results show overall seroprevalence of 98%, 47% and 95% for types 1, 2 & 3 respectively. The polio

seroprevalence in 2016 showed that all the three states (Bihar, Madhya Pradesh and Chhattisgarh) had >97% seroprevalence against poliovirus serotypes 1 & 2 and >92% for type 3. Type-2 immunity was the highest (99%) ever in 2016 attained in India among infants aged 6-7 months just prior to the tOPV-bOPV switch. These populations also had high mean titers against all three poliovirus serotypes in 2016. Due to the dependence of type-2 immunity on IPV, the seroprevalence against type-2 is expected to decline from the highest levels attained (99%) just prior to the OPV switch, especially in areas with low coverage in routine immunization. It is therefore important that a seroprevalence study be conducted in India to estimate the polio seroprevalence among cohort of infants born after the tOPV-bOPV switch. Due to existing threat of cVDVP2, it is programmatically important to keep the main focus on the assessment for type-2 immunity, especially in high- risk areas.

The 30th Meeting of the India Expert Advisory Group (IEAG, 19 May 2022, New Delhi) on polio eradication and 5th IEAG meeting on measles and rubella (MR) elimination (June 2023) have recommended that polio and MR seroprevalence study be conducted in India as soon as possible to understand the immunity gaps. As field operational aspects of the study for both polio and MR seroprevalence would remain same, except an additional milliliter of blood from participants, it was a good opportunity to include a nested study for MR seroprevalence as well. Keeping in view of the IEAG recommendations and to guide the polio endgame and MR elimination, WHO India in collaboration with partners, planned to conduct a polio and MR seroprevalence study in selected high-risk states/area.

2.0 Objectives of the study

Primary Objective:

- To assess the seroprevalence against type-2 poliovirus in selected high-risk states/area in India, among children 6-35 months stratified into 6-11 months, 18-23 months and 30-35 months of age

Secondary objectives:

- To understand the IgG antibody response against MR vaccination in the routine immunization schedule as a nested study
- To assess the seroprevalence against types 1 & 3 polioviruses in the studied age groups
- To compare seroprevalence between different study states
- To analyse vaccine (bOPV-IPV / MR) dose/response relationship to polio and MR seroprevalence

3.0 Study design

The study was designed to be a cross-sectional seroprevalence study of neutralizing antibodies against all three poliovirus types and IgG antibody for measles and rubella virus among children in the study ages residing in selected high- risk states. Children 6-35 months stratified into 6-11 months, 18-23 months and 30-35 months of age were enrolled. The study involved collection of about 2 ml of blood from subjects.

The states of Uttar Pradesh and Rajasthan (High Risk prioritization for poliovirus in India, measles outbreak), Maharashtra (The Global Certification Commission -Polio recommendation to undertake seroprevalence status of populations in the vicinity of the poliovirus essential facility, measles outbreak) and Assam (Most susceptible state for type 2 poliovirus from the seroprevalence study 2019 , measles outbreak) were selected for the study. Five districts have been selected from each polio high-risk and significant measles outbreaks (2022 & 2023) states of Uttar Pradesh and Rajasthan. For operational feasibility, one block was randomly selected out of all the blocks in the study districts. Assam had the same five districts/blocks as in 2019 polio seroprevalence study. In Maharashtra, the four blocks in the surrounding districts of Pune in 100 Kms radius of polio essential facility were selected along with a random ward from Mumbai. Thus, the study was conducted across five districts (and block) in each study state and 20 district/blocks (wards in urban areas) in the four study states.

Within each study block, 12 survey clusters were randomly selected. All census villages in the block or Census Enumeration Blocks (CEB) in the wards were included in the sampling frame for selecting study clusters. In each block/ward, 12 study clusters randomly selected from the sampling frame. This makes a total of 60 clusters in each study state. Six children were enrolled from each of the 12 clusters in the study block/ward. These six children were divided into two each from age groups of 6-11, 18-23, and 30-35 months. This arrangement provided 72 participants in each block/ward. Therefore, total targeted sample size was 360 participants in each state (6 children in each cluster X 12 clusters in each block/ward X 5 districts in each study state). The actual completion is presented in subsequent sections.

4.0 Study Implementation

The study was implemented broadly under five following phases:

A. Preparatory phase:

- Mapping & identifying study area clusters and allocating study areas to study field teams
- Micro-planning for screening of age eligible study participants by Field Facilitators (FF)

- Micro-planning for selection of study children
- Preparation of memory aid /event calendar for the local area
- Preparation of logistics at the district WHO India-NPSN SMO office
- Preparation of the study site facility

B. Four-step participant inclusion process:

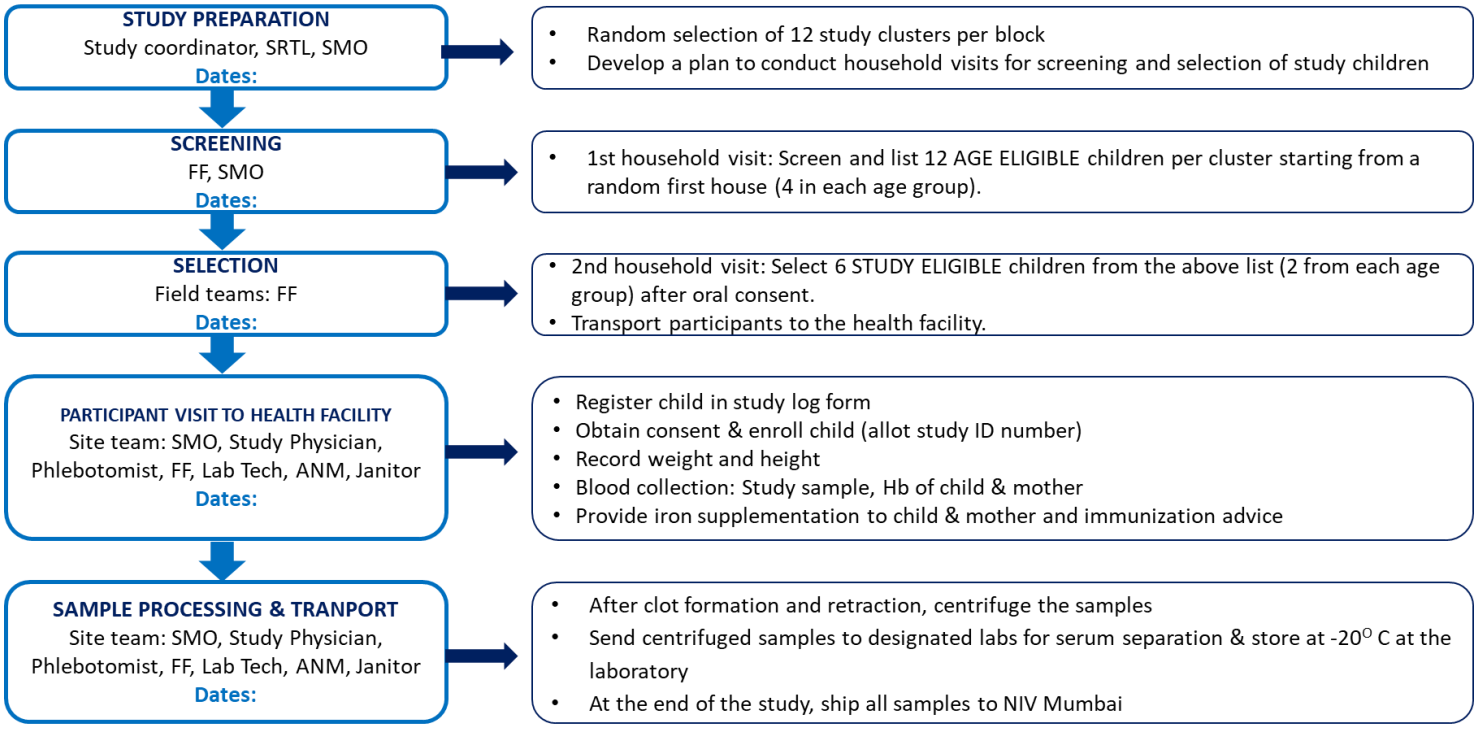
- Screening of age eligible children in the village/town
- Selection of study eligible children through household visits after oral consent
- Transportation of family to health facility

C. Informed written consent at health facility

D. Blood sample collection at the study health facility and other procedures

E. Processing, storage and shipment of samples

Study flow chart



5.0 Terms of reference for NielsenIQ (Survey agency)

The following terms of reference and study tasks were completed by NielsenIQ in close consultation and coordination with WCO India and WHO NPSN State Teams.

Study preparations:

- NielsenIQ attended all meetings called by WCO India for preparations, implementation and progress of the study. The meetings were at the Country Office, India, New Delhi.
- The survey questionnaire and SOPs for survey activities were finalized in coordination with WHO India.
- The survey implementation plan across the four study states along with study timelines were developed prior to start of the survey.
- NielsenIQ carried out the sampling of 12 Primary Sampling Units (PSUs), plus 2 back-ups in each of the five 5 blocks (one randomly chosen block in each study district) in the study states using Census 2011 data.
- The qualified and experienced field staff (Field Facilitators-FFs) for the study were recruited for respective study states, numbering 7 in one study block, totaling 35 in the 5 study blocks of a state, where survey activities were concurrently carried out in all the blocks in the state. The core team consisting of Survey national coordinators, National data manager and analyst and state survey coordinators were engaged during the survey activities.
- For survey questionnaire data entry, application was developed. It allowed data uploading on a daily basis. The final clean data is submitted to WCO India.
- The linelists, formats, questionnaires and consent forms are submitted to WHO NPSN State unit.

Training in the Study:

- The training materials and presentations were finalized in consultation with WCO India.
- The study coordinators' training was conducted at WCO India on March 6, 2024.
- The state level trainings were planned for respective states during April to August 2024.
- The designated staff for the survey, National coordinators, State coordinators and FFs attended the training planned by WCO India. Study MOs/DIOs and Phlebotomists also attended one day training.

Investigators meeting & preparedness review meeting (at WCO, India)
6 March 2024

- Each study block had a study site (mainly a PHC/CHC doing enrolment of subjects, blood sample collection & other study activities) supported by three field teams working in the study clusters (sending participants from households in the community to the study sites). Each study site had a Study Physician-MO one each of a Phlebotomist, one FF, ANM/nurse, laboratory technician, Cold chain handler and a Janitorial. The field teams had 2 FFs supported by a polio vaccinator (ASHA/AWW/Others) to cover a cluster for screening as well as for transportation on the day of blood sample collection at site. At district level, a district cold chain handler was designated for the study.

State Training: Maharashtra

State Training: Assam

State Training: Uttar Pradesh

State Training: Rajasthan

- Study ANMs/Nurse, Laboratory technicians, Cold chain handlers, Janitor in the study block trained locally in the district through a half day orientation by Study Site Coordinator (WHO SMO).

- In coordination with the local health authorities and responsible Surveillance Medical Officer/SRTL of WHO assigned for the study block, the study site was prepared as per the SOP for the activity.

Implementation of the study activities:

- The study was implemented as per the protocol, SOPs and trainings.
- Broadly, the study activities included preparatory activities as noted in the preceding paragraphs; Screening for age eligible infants and selecting study eligible children through household visits and transporting them to study sites. At the study site written signed consent was taken along with enrollment, blood sample collection, blood sample processing, blood sample transport from study site to district HQ. The samples from district HQ were then be shipped to designated state laboratories.
- The cold chain for the blood sample was maintained till it reached to the designated state laboratories.

Monitoring and supervision of the study activities:

The survey teams were supported by technical team along with the state monitors and coordinators. The monitoring and supervision were also carried out by WHO monitors during the study activities. Whenever required periodic orientation of staff was carried out to ensure best quality data through concurrent data cleaning and review meetings

Data management:

- Data was entered in an electronic tool (tablets/mobile based application).
- All the filled data was uploaded to a predefined server.
- The laboratory results will be merged with the field database using a common identifier
- This merged database will be the basis of further analysis.

Confidentiality and Ethical considerations:

- The highest level of ethics, safety and confidentiality were maintained during the survey activities. The study staff were instructed to maintain best demeanor for a smooth flow of participants at the study site.

Periodic progress and updates on the survey:

- Regular updates were shared with WCO India in the form of periodic progress reports.

6.0 Completion report

The following tables summarizes the achievements at different stages by states and at a study level:

Total completion at a Study level by States

State	No. of clusters screened	No. of household screened	No. of eligible children (6-35 months) found during Screening	No. of children (6-35 months) selected during selection and transport	Number of enrolled children (6-35 months) with blood draw completed
Rajasthan	60	6,257	817	362	360
Maharashtra	60	10,019	893	365	360
Assam	60	7,987	807	367	360
Uttar Pradesh	60	7,223	842	375	360
Total	**240**	**31,486**	**3,359**	**1,469**	**1,440**

Total completion at a Study level by Age group

Age group	No. of eligible children found during Screening	No. of children selected during selection and transport	Number of enrolled children with blood draw completed
E6 (6-11 Months)	1,131	496	480
E18 (18-23 Months)	1,131	486	480
E30 (30-35 Months)	1,097	487	480
Total (6-35 Months)	**3,359**	**1,469**	**1,440**

State: Rajasthan

District	Block/Ward	No. of clusters screened	No. of household screened	No. of eligible children* found during Screening	No. of children* selected during selection and transport	Number of enrolled children* with blood draw completed
Bharatpur	Sewar	12	1,357	173	72	72
Banswara	Bagidora	12	959	141	73	72
Jaipur	Bassi	12	1,479	163	73	72
Ajmer	Pisangan	12	1,427	169	72	72
Alwar	Kishangarhbas	12	1,035	171	72	72
Total		**60**	**6,257**	**817**	**362**	**360**

State: Maharashtra

District	Block/Ward	No. of clusters screened	No. of household screened	No. of eligible children* found during Screening	No. of children* selected during selection and transport	Number of enrolled children* with blood draw completed
Pune	Haveli	12	2,395	181	75	72
Satara	Khandala	12	2,477	177	73	72
Raigad	Khalapur	12	1,810	174	73	72
Ahmednagar	Parner	12	1,532	181	72	72
Mumbai	M-East	12	1,805	180	72	72
Total		**60**	**10,019**	**893**	**365**	**360**

State: Assam

District	Block/Ward	No. of clusters screened	No. of household screened	No. of eligible children* found during Screening	No. of children* selected during selection and transport	Number of enrolled children* with blood draw completed
Baksa	Mussalpur	12	1,412	159	72	72
Barpeta	Nityananda	12	1,575	153	72	72
Bongaigaon	Bongaigaon	12	1,830	177	73	72
Chirang	Sidli	12	1,839	150	74	72
Cachar	Sonai	12	1,331	168	76	72
Total		**60**	**7,987**	**807**	**367**	**360**

State: Uttar Pradesh

District	Block/Ward	No. of clusters screened	No. of household screened	No. of eligible children* found during Screening	No. of children* selected during selection and transport	Number of enrolled children* with blood draw completed
Badohi	Aurai	12	1,270	178	72	72
Pratapgarh	Pratapgarh Sadar	12	1,695	163	76	72
Lucknow	Buxi Ka Talab	12	1,408	158	75	72
Muzaffarnagar	Purkazi	12	1,700	166	73	72
Azamgarh	Lalganj	12	1,150	177	79	72
Total		**60**	**7,223**	**842**	**375**	**360**

**Children aged 6-35 months*