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Research Article

# Process Documentation of Post Introduction Evaluation of Rotavirus Vaccine in India

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## Abstract

**Background:** In 2016, India introduced the rotavirus vaccine (RVV) in the Universal Immunization Programme (UIP) to reduce the diarrheal disease burden in under-five children. In order to assess the programmatic experience and evaluate the impact of the introduction of RVV, RVV Post Introduction Evaluation (PIE) was conducted in the month of March 2022. The present study aims to document the experience of conducting the first ever digital post introduction evaluation in India.

**Methods:** RVV PIE was conducted among 14 government mandated states with two districts from each state and one block (planning unit) from each district to include a total of 28 facilities in 28 blocks. The standard WHO PIE questionnaire was adapted to a digital data collection tool for all the levels of health system and responders (National level, State, District, Health facility, Health worker, Caregiver questionnaires).

**Results:** The RVV PIE involved the following major steps- Development of survey tool, training of surveyors, response recording, data collation, data analysis, data visualization and reporting. RVV PIE tool covered the broad thematic areas of programme operations, training, supply chain, communication, innovation, surveillance and COVID-19 impact. Field teams comprised 64 evaluators from 16 immunization partner agencies. RVV PIE tool was used to capture responses from 309 stakeholders followed by automatic Visualization of selected Key Performance Indicators (KPIs).

**Conclusion:** The use of digital tools enabled efficient collation, analysis, and visualization of data, providing a comprehensive view of the program's Key Performance Indicators. Overall, the RVV PIE demonstrates the value of evaluating vaccine programs to ensure their success and sustainability.

***Keywords:*** *Immunization; Rotavirus Vaccines; Rotavirus; Evaluation*

## Background

Diarrhea is single-handedly responsible for about 9% of under-five deaths globally and 10% deaths of children aged less than 5 years in India amounting to around 110,000 deaths annually [1]. A number of microorganisms including bacteria and virus are known to cause

diarrhea. Among various causes, diarrhea associated with Rotavirus (RV) is the most common cause of diarrhea mortality and morbidity among children under five years of age. It is responsible for 29% of all diarrhea related deaths globally and 40% of moderate and severe diarrheal episodes in India [2]. Diarrhea is also an important contributor to long-term nutritional deficiency complications like stunting, wasting, malnutrition and loss of cognitive development potential. Rotavirus vaccination has consistently been found to be cost-effective and even cost-saving in most low- and middle-income countries (LMICs) when compared with no vaccination [3]. In their impact and cost effectiveness analysis in India, Rheingans R., *et al*. found that RV vaccination was very cost effective (cost-effectiveness ratio; $105-$298/DALY averted) even with the cost per dose as high USD 7.5 [4].

In 2016, India became the first country in the WHO Southeast Asia region to introduce the Rotavirus Vaccine (RVV) in the Universal Immunization Programme (UIP). Between 2016 and 2018, the introduction of RVV under UIP happened over three phases in 11 states. In September 2019, rapid scale-up of RVV in the remaining 25 states was achieved as a part of the '100 days agenda' covering the entire birth cohort of 26.7 million using two different indigenous RVV products namely Rotavac® and Rotasiil® [5]. Various clinical trials have been conducted worldwide to establish that these vaccines are safe, effective, efficacious and interchangeable [6].

According to World Health Organization (WHO) [7], all countries which have introduced a new vaccine should evaluate the impact on their vaccination system by conducting a post implementation evaluation (PIE) within 6 - 12 months following introduction. Such evaluation allows for early identification, documentation and correction of the problems associated with the introduction of the vaccine, so that these can be effectively prevented with tailored strategies while introducing new vaccine(s) in the future. The findings can also be shared with other countries to prevent similar problems, indicating the ease or complexity of the vaccine introduction. Since the tool provided by WHO is generic and provides overarching guidance for conducting PIE, a country like India which is diverse both geographically and demographically, needed the tool to be modified and contextualized. The main objectives of the RVV PIE were to:

1. Assess the implementation process of the introduction of the RVV in the UIP to provide lessons for future vaccine introductions.
2. Capture the implementation and learnings of RVV product switch in select states.
3. Evaluate the overall impact of the introduction of RVV on India's national immunization programme.
4. Identify strengths and gaps in the immunization programme in general to guide health system strengthening and future vaccine introductions.
5. Assess the impact of the COVID-19 pandemic on the Routine Immunization (RI) programme.

Considering the already overdue timeline and the on-going COVID 19 pandemic at the time of inception of the exercise, it was decided to develop and utilize a digitized version of the contextualized WHO PIE tool.

## Aim of the Study

The present study aims to document the experience of conducting the post introduction evaluation for RVV in India and chronicle the processes followed during the exercise.

## Methodology and Result

### RVV PIE Process

The RVV PIE was stewarded by the Ministry of Health and Family Welfare (MoHFW), Government of India (GoI) and coordinated by John Snow India (JSI) for a period of nine days, between 21st and 29th March, 2022. The RVV PIE involved the following major steps- Development of survey tool, identifying investigators, sampling, training investigators, data collation, data analysis, data visualization and reporting.

## Development of PIE tool

Data collection tool for the PIE was adopted and adapted from the standard WHO PIE questionnaire for all the levels of health system and responders (National level, State-level, District level, Health facility, Health worker, Caregiver questionnaire). The PIE tool was developed in close collaboration with the GoI and covered the broad thematic areas of programme operations, training, supply chain, communication, innovation, surveillance and COVID-19 impact. The WHO tool was contextualized to India in order to capture the nuances of the introduction of RVV and its scale-up. The key consideration for inclusion of questions was relevance to the program since it felt pertinent to collect the maximum amount of data in the shortest duration of time. The questionnaires were finalized after incorporating inputs from MoHFW. An agency was hired to develop the digital version of the tool. In order to digitize the conventional PIE, the questionnaire was comprehensively structured with a minimum number of open-ended questions. Further, the questions were organized sequentially to ensure a natural progression in the responses. The digital questionnaire had features such as response validations, character limits and offline response storage to ensure seamless, user-friendly interface by the PIE investigators.

## Sampling

As per the WHO recommendation, PIE was conducted in minimum six regions to provide adequate information on the new vaccine introduction under consideration. However, given the diversity of the country, phase-wise introduction, usage of different types of RVV products under UIP, and recent transitioning of the RVV products, 14 states were included covering all zones of India. It was ensured that states from each phase of introduction and with different RVV products under the UIP were included.

The present study followed a multi stage purposive sampling as depicted in the flow chart (Figure 1). In each of the RVV PIE state, a good and a not-so-good performing district was included based on its inclusion in the Intensified Mission Indradhanush (IMI)(National program to improve coverage in poor performing districts), vaccine availability index 2021-22 (calculated as percentage based on the number of days the vaccine was available in the district throughout the month) and the female literacy rate (from NFHS-5) as a demand-side parameter for the non-IMI districts. It was ensured through convenience sampling that the selected IMI district has the lowest vaccine availability index while the selected non-IMI district has the highest female literacy rate for that state. The States and districts selected for the RVV PIE is given in table 1. The sampling culminated in the overall selection of 14 states, 28 districts, 28 health facilities, and 28 health sub-centers.

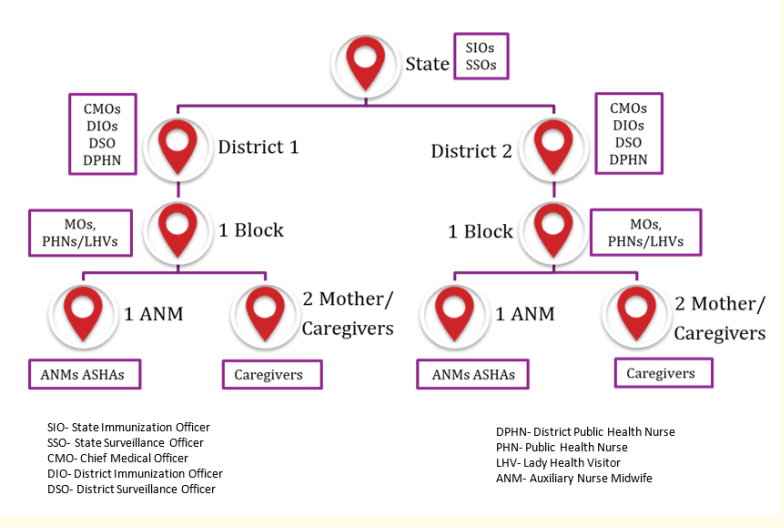


***Figure 1:*** *Flowchart depicting sample selection during the study.*

| Sr. No. | State | Geographical Zone | Districts | | RVV product Rotavac®/Rotasiil® lyophilized | Phase of RVV introduction | Transitioning of products (Rotasiil® Lyophilized/Rotavac® to Rotasiil® liquid |
|---|---|---|---|---|---|---|---|
| | | | IMI | Non-IMI | | | |
| 1. | Assam | North-East | Tinsukia | Kamrup (Metro) | Rotavac® | Phase-2 | __ |
| 2. | Bihar | East | Patna | Jehanabad | Rotavac® | Phase-4 | __ |
| 3. | Delhi | North | East district | South-west district | Rotavac® | Phase-4 | __ |
| 4. | Gujarat | West | Kheda | Ahmedabad | Rotasiil® | Phase-4 | Rotasiil® Lyophilized to liquid |
| 5. | Karnataka | South | Bengaluru (Urban) | Dakshina Kannada | Rotasiil® | Phase-4 | Rotasiil® Lyophilized to liquid |
| 6. | Kerala | South | Thiruvananthapuram | Kottayam | Rotasiil® | Phase-4 | Rotasiil® Lyophilized to liquid |
| 7. | Madhya Pradesh | Central | Jabalpur | Indore | Rotavac® | Phase-2 | __ |
| 8. | Maharashtra | West | Pune | Nagpur | Rotasiil® | Phase-4 | Rotasiil® Lyophilized to liquid |
| 9. | Odisha | East | Cuttack | Puri | Rotavac® | Phase-1 | Rotavac® to Rotasiil® liquid |
| 10. | Punjab | North | Faridkot | SAS Nagar | Rotavac® | Phase-4 | __ |
| 11. | Rajasthan | West | Dausa | Pali | Rotavac® | Phase-2 | __ |
| 12. | Tamil Nadu | South | Thiruvallur | Vellore | Rotavac® | Phase-2 | Rotavac® to Rotasiil® liquid |
| 13. | Uttar Pradesh | North | Lucknow | Baghpat | Rotavac® | Phase-3 | __ |
| 14. | West Bengal | East | North 24 Parganas | Kalimpong | Rotasiil® | Phase-4 | Rotasiil® Lyophilized to liquid |

***Table 1:*** *States and Districts selected for the RVV PIE.*

## PIE Investigators

A three-member team of experts was appointed to train the evaluators, oversee the PIE and present the findings to the MoHFW. The team comprised a lead, a co-lead and a senior advisor. This has been a standard protocol in PIE to ensure that the PIE remains an independent process and is not influenced by the government, the donor, or the implementing organization. All communication to the evaluators was sent out in the name of these experts.

The MoHFW identified 17 organizations and institutions in the country, which had expertise in immunization. These identified organizations and institutions nominated the evaluators from among their staff at state, regional, and district levels. The finalized field teams comprised 64 evaluators from 16 immunization partner agencies with a mix of experts, scientists, practitioners and clinicians. A team

was formed from among the evaluators to conduct the interviews at the national level. For each state, two teams (with 2 members each) were formed, which carried out the evaluation in both the districts. The team which was close to the state capital, filled tools for state level officials. Field observation visits and interviews were conducted by the team in each selected district using digitized version of the RVV PIE tool. It was ensured that at least one person from among the team knew the regional language of that state to ensure ease of communication at the health sub-center and community level and would eliminate the requirement of interpreters/translators, which ran the risk of loss of information. Information regarding RI session schedules and the RI centers in the district/blocks was procured from states in advance to the day of PIE.

### Setting up of the centralized control room

In order to ensure smooth execution of the RVV PIE a centralized control room was set up to coordinate with partners, states and districts to facilitate seamless logistical arrangements. Throughout the duration of the RVV PIE, real-time mitigation of any issues faced by the evaluators in the field was ensured while simultaneously keeping track of the number and success of questionnaires submitted each day. The centralized control room, set up at the national office of JSI in New Delhi, ensured ironing out of any logistical, technological or technical issues. Coordinating with digital agency for troubleshooting of doubts and issues reported by the evaluators real-time.

### The PIE: Field work/data collection

At the state level, the evaluators completed the state-level questionnaire with SSIO and explained their plan of visiting the district and block, and planned the visit to the district/block/health facility/RI session.

At the district level, the team completed the district level questionnaire with the DIO. After explaining their plan to visit the specific blocks, the team availed details of the MOIC of the selected blocks. They then visited the district vaccine store and planned their visit to the block. At the block level, the team completed the health facility level questionnaire with the MOIC, explained their plan of visiting the session sites and availed details of the health workers. At the sub-center, the ANM from the selected block who had been involved during RVV introduction was interviewed along with two mothers/caregivers. Interviews at the health sub-center level and with caregivers were conducted on RI days in all states. This was done to ensure the presence of caregivers and also to observe the vaccinators' practices.

As this was a digital PIE, all teams were provided with a tablet each, which had a built-in digital PIE tool that could be accessed online as well as offline through a dedicated user ID and password for each district. The evaluators were expected to inform the central control room about any deviation in plan (change in respondents, not being able to fill in the questionnaires, difficulties in visiting selected geographies, etc). Each team spent 2 - 3 days in the respective assigned districts. Each questionnaire took approximately 1.5 - 2 hours to complete. The fieldwork at session sites was planned keeping in mind the timings of vaccination session.

### Data analysis and drafting of recommendations

The digitized PIE tool allowed real time automated descriptive data analysis of the collected data. Qualitative data analysis of the open-ended questions was done using the NVIVO software. Once preliminary results emerged, findings were shared with State level officials. Following this, a national workshop was organized for the team of evaluators to meet after they returned from the field to deliberate over these findings. Participants were divided into 10 teams based on thematic areas covered under the PIE. Each thematic team was responsible for presenting the findings, analyses and suggested recommendations to the group. The presented findings, analyses and recommendations went through a few revisions based on the feedback received from experts and senior evaluators. The analyses and recommendations for the 10 thematic areas were then collated and a presentation was prepared for MoHFW officials.

## Discussion

The RVV PIE was successfully conducted in India between 21st and 29th March, 2022 across 14 states, 28 districts, 28 health facilities, and 28 health sub-centers using the novel digitized version of the modified WHO PIE Tool. Despite best efforts, few challenges posed

during the exercise which were addressed during the RVV PIE implementation. An unforeseen shift in a larger national-level immunization drive (Polio Ravivaar) from January to February 2022 affected the dates of the RVV PIE causing unforeseen delays. However, this was managed by rescheduling the PIE to the next earliest slot in March 2022. All the relevant personnel were informed in good time about this change to ensure continued support and cooperation. Another challenge was with the poor internet connectivity in certain areas which hampered the otherwise seamless experience with the digitized PIE Tool. The digital tool was modified to allow recording of offline data which would be updated on the server once internet was available. Since the present PIE was conducted more than 12 months after the introduction of the vaccine, it inherently ran the risk of missing problems related to the introduction that could have been easily corrected, such as weaknesses related to training, vaccine handling and management, or vaccine distribution.

Considering the rich experience of the RVV PIE a few recommendations for future PIEs must be highlighted. First and foremost, it must be emphasized that in the future, PIEs need to conducted within 6-12 months of introduction any new vaccine to decrease recall bias in the data collection. This is because the constant flux in the staffing situation might result in missing out on the health staff which was involved in the introduction process. Additionally, to ensure a smooth flow of communication between the Centre and the States and to ensure timely response, rigorous follow-up is required with a nodal person assigned for such communication and coordination. This person can be either an official in the Ministry or a partner acting on behalf of the Ministry. At the same time, a complete buy-in of the evaluation by the Central Government can speed up processes.. For collecting the sub-state data, planning should be done in such a way that there should be sufficient time, so that all the desired information can be collected well on time. Planning and collation of sub-state data can be done early. The states and districts can be clearly informed regarding the dates and objectives of evaluation so that the desired information is readily available. Furthermore, to ensure a thorough orientation of evaluators, two days can be allocated instead of one day. Future PIEs could perhaps have a more robust sampling strategy with blocks selected randomly instead of convenience sampling. Since an informed visit could result in pre-emptive preparedness by the field staff, future PIEs could have random uninformed visits to session sites on designated RI days.

The present PIE exercise also brought forth few recommendations made by an expert group which included inclusion of an option to view the submitted forms that will allow the evaluator to review the data at a later stage. Another suggestion was to provide in-built feature in the tool that allows data comparison between state level data with district, health facility, health worker level etc. The group also recommended that the government could consider using the digital tool for all PIEs in the future. Additionally, the need for more detailed SOPs for the evaluators was highlighted to ensure better quality data collection. It was also emphasized that PIE should be conducted in close collaboration with immunization partners perhaps with a greater participation of international representatives from partner and donor organizations. Furthermore, It was also suggested that following PIE, a brief report in the form of a newsletter could be prepared highlighting key gaps and recommendations to be shared by the Centre with all state officials. Furthermore, physical/virtual meetings should be organized for all the key state officials so that there is a healthy exchange of experience sharing in a timely and efficient manner.

## Conclusion

In conclusion, the RVV PIE conducted in India using the digitized version of the WHO PIE Tool was a successful undertaking. Despite the unforeseen shift in the national-level immunization drive which caused delays rescheduling the RVV PIE was effectively managed. Addressing poor internet connectivity, the digital tool was modified to allow offline data recording. Recommendations for future PIEs include rigorous follow-up, complete buy-in from the Central Government, assigning a nodal person for coordination, early planning and collation of sub-state data, two-day orientation for evaluators, random uninformed visits, additional features in the tool, collaboration with immunization partners, and sharing key findings through newsletters and meetings.

## Contributorship Statement

Rashmi Mehra- Drafting the article.

Arindam Ray- Conception or design of the work, Critical revision of the article.

Veena Dhawan- Conception or design of the work, Critical revision of the article, Final approval of the version to be submitted.

Rhythm Hora- Drafting the article.

Amanjot Kaur- Data collection.

Syed F Quadri- Data collection.

Seema S Koshal- Critical revision of the article.

Amrita Kumari- Critical revision of the article.

Pradeep Haldar- Final approval of the version to be submitted.

Arup Deb Roy- Conception or design of the work, Final approval of the version to be submitted.

## Ethics Approval and Consent to Participate

Not applicable.

## Consent for Publication

Not applicable.

## Availability of Data and Materials

Not applicable.

## Competing Interests

The authors declare that they have no competing interests.

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