FOURTEENTH INTERNATIONAL

ROTAVIRUS SYMPOSIUM

MARCH 14–16 **2023** BALI INDONESIA

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Rotavirus Vaccine Product Switch: Experience From the Universal Immunization Programme in India

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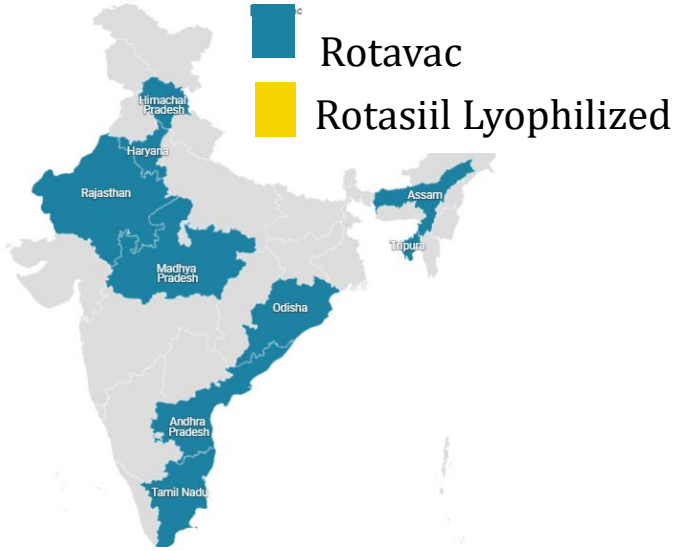
JSI India

Next 15 Minutes

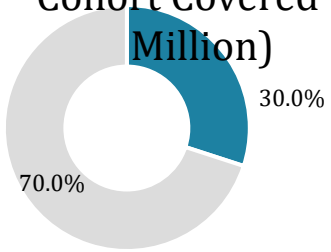
1. Rotavirus Vaccine (RVV): Product Diversity & Timeline
2. Vaccine Product Switch Learnings
3. RVV Product Switch: Drivers & Challenges
4. RVV Product Switch: Process & Evalution
5. Product Switch: Way Forward

Rotavirus Vaccine (RVV): Product Diversity & Timeline

Rotavirus Vaccine: Introduction and Scale-up in India with Indigenous Products

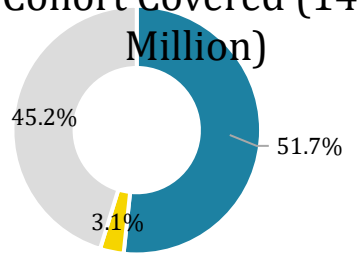


Cohort Covered (8 Million)

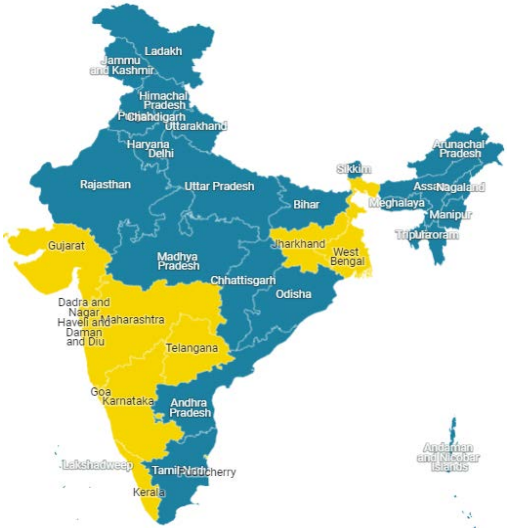


2016-17

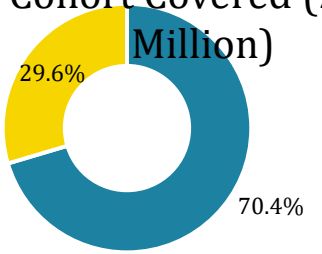
Cohort Covered (14.6 Million)



2018

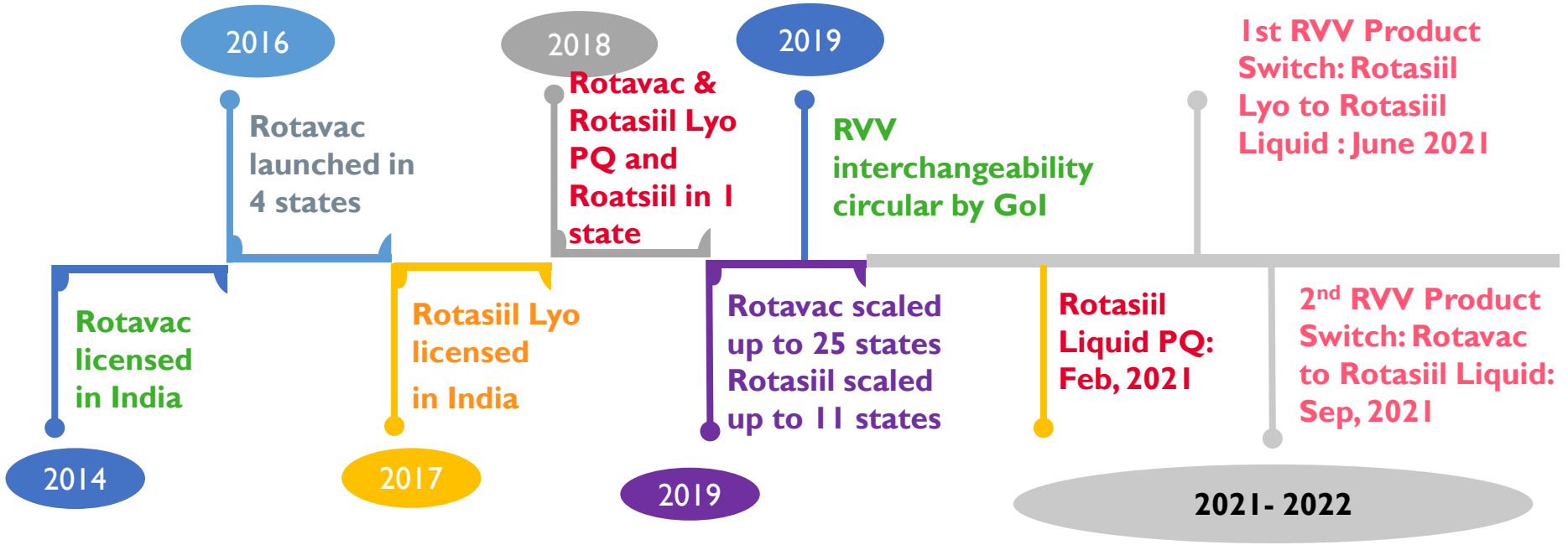


Cohort Covered (26.7 Million)



2019

Rotavirus Vaccine Products Timeline under UIP in India: 2016 to 2022



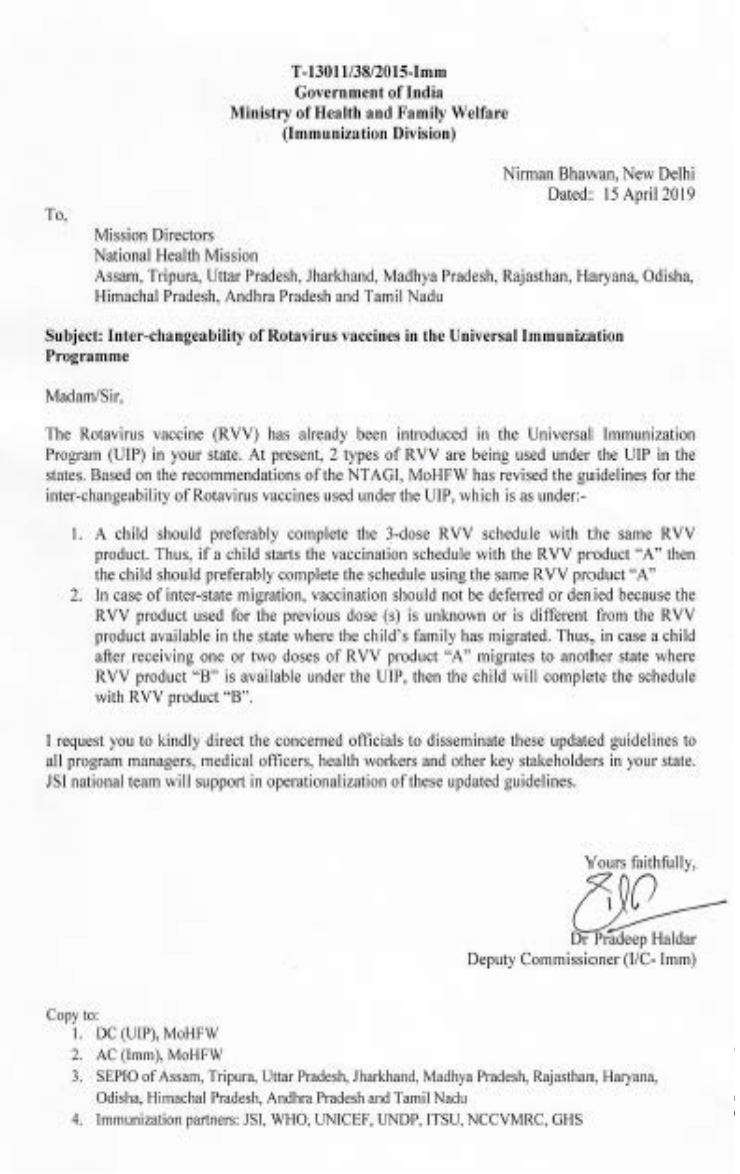
- For the 1st time, two different products were used in India's immunization program.
- For the first time, a single dose vaccine presentation got introduced in the UIP in India

Indian RVV Products Characteristics

Discussion Point	Rotavac	Rotasiil – Lyophilized	Rotasiil – Liquid
Presentation	5 dose	2 dose	1 dose
Form/Type of product	Liquid frozen	Lyophilized	Liquid
Presentation	Vial	Two vial set	Strip of 5 single tubes
VVM	Type 2	Type 30	Type 7
Strains present in vaccine	G9P[11]	G1, G2, G3, G4, and G9	G1, G2, G3, G4, G9
Doses in each presentation	5 drops	2.5 ml	2 ml
WHO PQ decision	Jan 2018	Sep 2018	Feb 2021
Schedule	3 doses at 6, 10 & 14 weeks	3 doses at 6, 10 & 14 weeks	3 doses at 6, 10 & 14 weeks
Reconstitution	Not needed	Needed	Not needed
Storage temperature	-15 to -25 ^{0} C (SVS, RVS, DVS) +2 to +8 ^{0} C (at sub-district stores/CCPs)	+ 2 to +8 ^{0} C (at all levels)	+ 2 to +8 ^{0} C (at all levels)
Cold chain volume per dose	4.2 cubic cm	10.5 cubic cm	19.9 cubic cm
Product bundling per vial	Dropper	One adapter and two 6 ml syringes	No other logistics

RVV Interchangeability for Vaccine Recipient

- Beside India, 7 more countries were using mixed RV effectiveness concern
- All mixed vaccine schedules are shown to be non-i schedule for Rotateq and Rotarix (Libster, 2016; Pa
- ACIP prefers that doses of vaccine in a series come however, if this is not possible or if the manufactu unknown, providers should administer the vaccine
- If different brands of a particular vaccine require a series completion (e.g., Hib and rotavirus vaccines) higher number of doses is recommended for series either rotavirus or Hib vaccines)
- **Based on this evidence, on 15 April 2019 the GoI a of RVVs**
  - **Migrant children from one state to another**
  - **Children coming from private to public sector**
- Further studies conducted, on the recommend interchangeability evidence between Rotavac a (Kanungo et al. 2022)



T-13011/38/2015-Imm
Government of India
Ministry of Health and Family Welfare
(Immunization Division)

Nirman Bhawan, New Delhi
Dated: 15 April 2019

To,

Mission Directors
National Health Mission
Assam, Tripura, Uttar Pradesh, Jharkhand, Madhya Pradesh, Rajasthan, Haryana, Odisha, Himachal Pradesh, Andhra Pradesh and Tamil Nadu

Subject: Inter-changeability of Rotavirus vaccines in the Universal Immunization Programme

Madam/Sir,

The Rotavirus vaccine (RVV) has already been introduced in the Universal Immunization Program (UIP) in your state. At present, 2 types of RVV are being used under the UIP in the states. Based on the recommendations of the NTAGI, MoHFW has revised the guidelines for the inter-changeability of Rotavirus vaccines used under the UIP, which is as under:-

1. A child should preferably complete the 3-dose RVV schedule with the same RVV product. Thus, if a child starts the vaccination schedule with the RVV product "A" then the child should preferably complete the schedule using the same RVV product "A"
2. In case of inter-state migration, vaccination should not be deferred or denied because the RVV product used for the previous dose (s) is unknown or is different from the RVV product available in the state where the child's family has migrated. Thus, in case a child after receiving one or two doses of RVV product "A" migrates to another state where RVV product "B" is available under the UIP, then the child will complete the schedule with RVV product "B".

I request you to kindly direct the concerned officials to disseminate these updated guidelines to all program managers, medical officers, health workers and other key stakeholders in your state. JSI national team will support in operationalization of these updated guidelines.

Yours faithfully,

Dr Pradeep Haldar
Deputy Commissioner (I/C- Imm)

Copy to:
1. DC (UIP), MoHFW
2. AC (Imm), MoHFW
3. SEPIO of Assam, Tripura, Uttar Pradesh, Jharkhand, Madhya Pradesh, Rajasthan, Haryana, Odisha, Himachal Pradesh, Andhra Pradesh and Tamil Nadu
4. Immunization partners: JSI, WHO, UNICEF, UNDP, ITSU, NCCVMRC, GHS

Vaccine Product Switch Learnings

Global Learnings of Vaccine Product Switch

- Dissemination of immunization guidelines, and plans for supervision, monitoring, and evaluation, including providing feedback to health workers and staff at all levels and advocacy and social mobilization activities around the introduction of the new vaccine help smooth switching.
- The development and use of a standardized monitoring template is needed to collect information in order to assess the switch proceses.[1]
- The value of extensive engagement of national immunization programs based on risk identification, strategic planning & implementation lies in bringing particular focus on vaccine supply, logistics, communication, health worker training, and monitoring for routine immunization.[2]

[1](https://www.unicef.org/eap/sites/unicef.org.eap/files/2018-04/The%20Switch%20From%20Trivalent%20to%20Bivalent%20Oral%20Poliovirus%20Vaccine%20in%20the%20Sou..._0.pdf)

[2] Bahl S, Hasman A, Eltayeb AO, James Noble D, Thapa A. The Switch From Trivalent to Bivalent Oral Poliovirus Vaccine in the South-East Asia Region. J Infect Dis. 2017 Jul 1;216(suppl_1):S94-S100. doi: 10.1093/infdis/jiw602. PMID: 28838177; PMCID: PMC5853811.

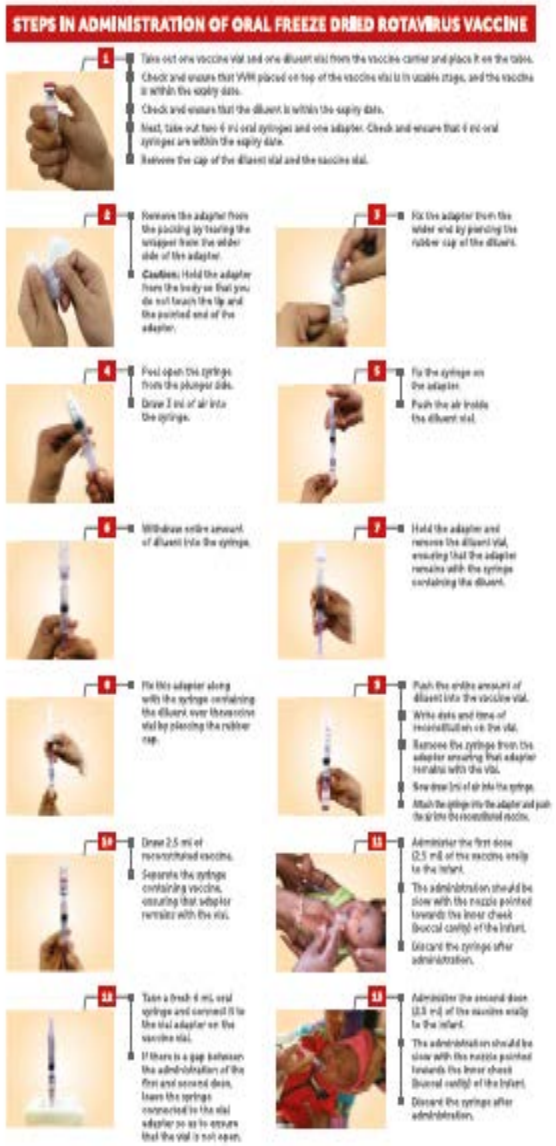
India's Previous Vaccine Switch Experiences

Vaccine Switch	Year of Switch	Scale	Lessons
DPT to Pentavalent (DPT+HepB+Hib)	2011-2015	National	• The schedule remains the same • Mode of administration same • Meticulous calibration of phasing in of Penta while phasing out DPT to prevent stock-out • Reporting in National HMIS needs updating • DPT also continued as booster dose
tOPV to bOPV	2016	National	• Intensive field & CC point monitoring done to detect and inventory residual tOPV, even for private sector
Measles to Measles Rubella	2017	National	• Switch happened through large scale campaign • Had to toggle between 5 dose & 10 dose vials • Had to manage different diluents specific to the vaccines • Detailed supply chain and session guidelines used in training FLWs
TT (Tetanus Toxoid) to Td (Tetanus and Diphtheria)	2018	National	• Prompted by age-shift of diphtheria, detected by active DPT surveillance • Smoothest of all product switches, as route, age, dose and presentation – all remain the same

RVV Product Switch: Drivers & Challenges

Drivers For RVV Vaccine Product Switch in India

- Challenges with existing products as identified through monitoring and post-introduction evaluation
  - **Rotavac**:
    - Dropper mismatch with OPV
    - Uncertainty around use beyond 6 months storage at 2-8 C
    - Placement of VVM (cap vs vial)
  - **Rotasiil Lyophilized**
    - Difficult vaccine administration procedure
    - High requirement of dry storage space
- Geographic expansion and increasing coverage requiring uninterrupted supply and flexible supply chain management
- Changing product lines from the licensed manufacturers



Challenges in RVV Product Switch in India

- **Training:**
  - The operational guidelines and training material needs to be customized for the new RVV product, as the vaccine has different presentation, doses, etc.
  - Retraining of the entire healthcare workforce in the country (~5.57 M)

- **Cold Chain:**
  - Both type of RVVs have different temperature and space requirement and therefore separate assessments required
  - Modifications in the Supply chain, data management tools/platforms
  - Monitoring ~30,000 cold chain points

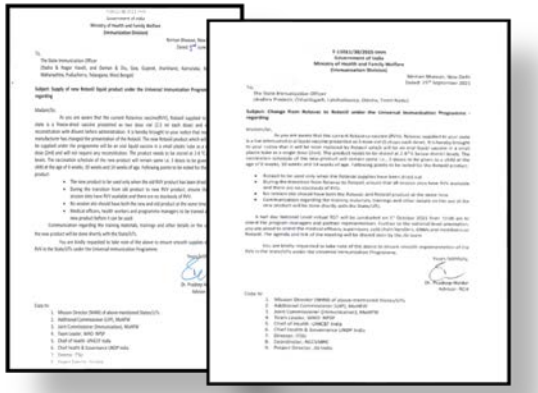
- **Interchangeability of Vaccine:**
  - Ensuring that interchangeability guidelines for the individual child and the programme reach every health worker
  - So far, the product switch affected ~49.7 % of India's birth cohort

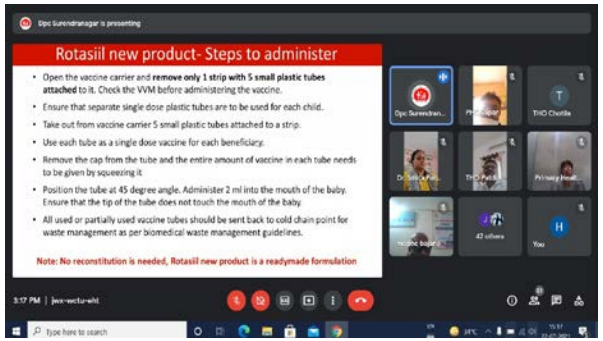
- **Switch during the pandemic:** Conducting trainings, monitoring supply chain, monitoring immunization sessions stretched the system

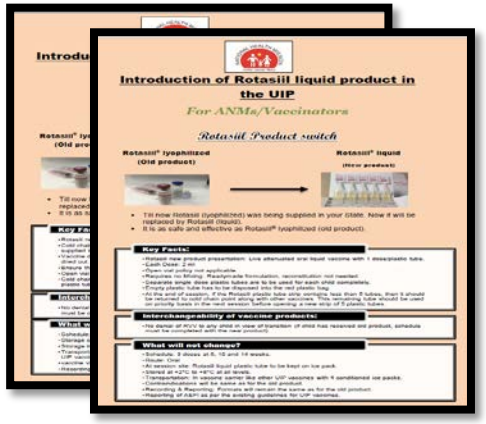
RVV Product Switch: Process & Evalution

RVV Product Switch Process: India

- Single-dose Rotasiil® liquid (oral liquid vaccine in single-dose small BFS tubes), got licensed for use under UIP in 2021
- **Guidelines** issued by GoI in mid-2021:
  - **The new product was used only when the old RVV product dried out (EEFO)**
  - **Ensured that all session sites have RVV available of at least one type**
  - **No session site had both the new and old products at the same time**
  - **No PHC was given a new product if >21 days supply of old product was available**







- **Job aids** developed, disseminated
- Leveraged **virtual platform** for hybrid training during the pandemic
- Robust **operational and communication planning**
- Intensive **monitoring of supply chain** through **electronic vaccine intelligence network** (eVIN)

Post-Introduction Evaluation of Product Switch

- All the 7 states evaluated for product switch in PIE, **issued formal communication** to the districts about new RVV product switch mentioning the key guidelines. These guidelines were further shared to the blocks and sub-block levels.
- In all the districts/health facilities surveyed, **training has been provided to all the health personnel for the product switch**.
- Overall, the respondents in these 7 states reported that the product switch activities were more or less smooth.
- The new single dose **liquid product being easy to administer, time-saving and with minimal wastage** has been welcomed by all.
- **All the districts are using eVIN to track the vaccine stock availability**. Around 50% of the districts also took declarations from the block about the available stock of old RVV products before the supply of the new product, to ensure compliance with GoI guidelines.
- **No mixing of products was observed at any session site**.
- However, only 50% of the districts evaluated, reported the distribution of job aids to health workers.
- At the health facility level, only 40% of the districts reported having received job aids from the districts.
- About 71.4% of health workers interviewed were aware that RVV products were interchangeable.

RVV Product Switch: Way Forward

- Every country context is unique, requiring localized meticulous planning before implementing product switch
- Heterogeneity of products demands repeated training of the health workforce and need-based communication to the beneficiaries
- Digital supply chain solutions and simple graphic job aids are helpful tools to facilitate the switching process
- Intensive monitoring is required to detect and mitigate any programme error in terms of product mix-up, missed doses, and programmatic confusion in the field.
- Studies have found single-dose vaccine presentation, being of the lowest wastage, lowest risk of contamination, and easiest to calculate requirement, to be more cost-effective by reaching of children at optimal number of doses.[1]
- RVV liquid single-dose product is found to be better accepted for overall ease of use, provided the programme has adequate storage and waste management in place.
- Going forward, the countries may like to use Total System Effectiveness (TSE) framework[2] to decide on development and switch to innovative products

(1) https://pubmed.ncbi.nlm.nih.gov/14758432/
(2) https://www.sciencedirect.com/science/article/pii/S2590136220300255

Partners who supported Government of India in RVV introduction

World Health Organization

सत्यमेव जयते

Ministry of Health & Family Welfare

Government of India

unicef

UNDP

JSI INDIA

BILL & MELINDA GATES foundation

आरोग्यं सुखसम्पदा

ITSU

IMMUNIZATION TECHNICAL SUPPORT UNIT

Ministry of Health & Family Welfare

THE INCLEN TRUST INTERNATIONAL