

ROTAVIRUS VACCINE THE INDIA STORY

Immunization Division
Ministry of Health & Family Welfare
Government of India





This book is dedicated to every child of India and beyond who dreams of a world full of equal opportunities...

*“Where the mind is without fear
and the head is held high,
where knowledge is free,
where the world has not been broken up into fragments by narrow
domestic walls.
Where words come out from the depth of truth,
where tireless striving stretches its arms towards perfection.
Where the clear stream of reason has not lost its way
into the dreary desert sand of dead habit.
Where the mind is led forward by thee
into ever widening thought and action...”*

From Rabindranath Tagore's, *Gitanjali*, Song offerings





In 2016, India became the first country in the WHO-South East Asian region to launch a Rotavirus vaccine developed indigenously, by Indian scientists and manufactured by an Indian producer.

In 2019, India becomes the first country in the region to scale-up the Rotavirus vaccine nationally across 29 states and 8 union territories, with domestic funding. Gavi came forward to support the vaccine cost in one state, Uttar Pradesh in 2018.

Through the ambitious “100-days agenda”, the government expanded the Rotavirus vaccine to all states and union territories between July and September 2019.

Currently, India produces two WHO-prequalified Rotavirus vaccines. At less than a dollar-a-dose, these vaccines have become game-changers in India’s efforts to reduce under-five mortality in India and beyond.





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10 Dose Vial 5 mL
रोटोवायरस वैक्सीन (लाइव
रटुनेटेड, ओरल) आई पी
Rotavirus Vaccine
(Live Attenuated, Oral) IP
ROTAVAC
For oral administration only.
Not for injection.
CGS NOT FOR SALE

Each dose of 0.5 mL. Contains
Rotavirus Vaccine = 5 U.I. to 5 U.I.
Adsorbed on Aluminium
Phosphate (AMP) = 1.5 mg
Preservative: Chlorhexidine 1% 0.01% w/v
Other: 0.5 mL, Individually
Sealed between 2°C and 8°C
NOT TO BE FROZEN
NOT TO BE STORED IN ICE
COMPARTMENT

INTRODUCTION

With about 27 million infants in more than 600,000 villages, India runs the largest immunization programme in the globe. Being launched in 1978, India's vaccination programme is one of the oldest in the world. With huge topological diversity – from snow peaked mountains to roaring oceans, from desert sands to flooded plains, from throbbing cities to tropical forests – India presents the most challenging terrains, to reach their last mile children. With more than 100 languages, 1,600 dialects and seven religions, India offers one of the most dynamic, multi-cultural demographics to engage. With six medical systems and about 16 percent private share of immunization services, India poses one of the most complex health systems in the world.

After seven long years of launch of Expanded Programme on Immunization in 1985, India made vaccination services universal for every child. But it continued to remain home to the most number of unimmunized children in the world. In the last decade, India's full immunization coverage remained stagnant around sixty percent. India continues to have the largest share of Rotavirus illness and deaths in the world.

But then, India has turned around its immunization programme with all the urgency to serve the children who need it most. In 2014, Hon'ble Prime Minister Shri Narendra Modi announced the launch of four new vaccines in India's Universal Immunization Programme. Out of these four, Rotavirus vaccine has been the first on the priority list to save children from this deadly diarrhoeal disease. In 2015,

the Hon'ble Prime Minister launched the first indigenously developed and manufactured Rotavirus vaccine. And, in March 2016, India became the first country to introduce Rotavirus vaccine in the national immunization programme in WHO South East Asia region.

In 1985, the same year that India rechristened its vaccination services as Universal Immunization Programme, some brilliant medical researchers at the All India Institute of Medical Sciences, New Delhi discovered a novel Rotavirus strain which led to rigorous research and development through international collaboration for the next three decades to develop India's first Rotavirus vaccine. India didn't stop there. A second Rotavirus vaccine has been developed and both the vaccines have now got WHO pre-qualification for global use. India supplies more than sixty percent essential vaccines to the developing world. The Indian Rotavirus vaccines, being more affordable and programme compatible, offer new promise of life to the children around the globe.

In 2014 India launched its special immunization drive Mission Indradhanush in selected districts with low immunization coverage, which got intensified in its focus and reach in 2017 to reach each and every child. Through this campaign approach, India has delivered the benefit of vaccines to more than 8 million pregnant women and over 33 million children.

An unwavering political commitment to overcome every challenge, a seamless public-private social innovation partnership, an evidence-informed decision process, and a comprehensive strategy leveraging the

strength and support of every stakeholder, including Indo-US Vaccine Action Programme and Gavi, contributed to India's success in the fight against Rotavirus.

This book captures India's fascinating and inspiring journey of discovering, developing, and delivering the Rotavirus vaccine to the world's largest birth cohort through the world's largest immunization programme, to stimulate actions for the present and synthesize learnings for future. This book celebrates the glorious success of India's brilliant scientists who turn inspirations into innovations. This book recognises the relentless efforts of the entrepreneurs who make "Make in India" a dream destination. This book chronicles the cooperative federalism of governance in vaccination programme striving towards hundred percent coverage and equity.

This book champions the voices of people in harmony with vision of the premiers to translate promises into passion, passions into programme. This book epitomises unity among diversity – by telling stories in all colours of *Indradhanush*, for one vaccine, one nation. This book in its content and creation, patronises the partnership.

This book is a tribute to every parent who continue to vaccinate their own kids and motivate others. It is a tribute to frontline workers, medical fraternity and community leaders from all walks of life who build and maintain people's trust in vaccines.

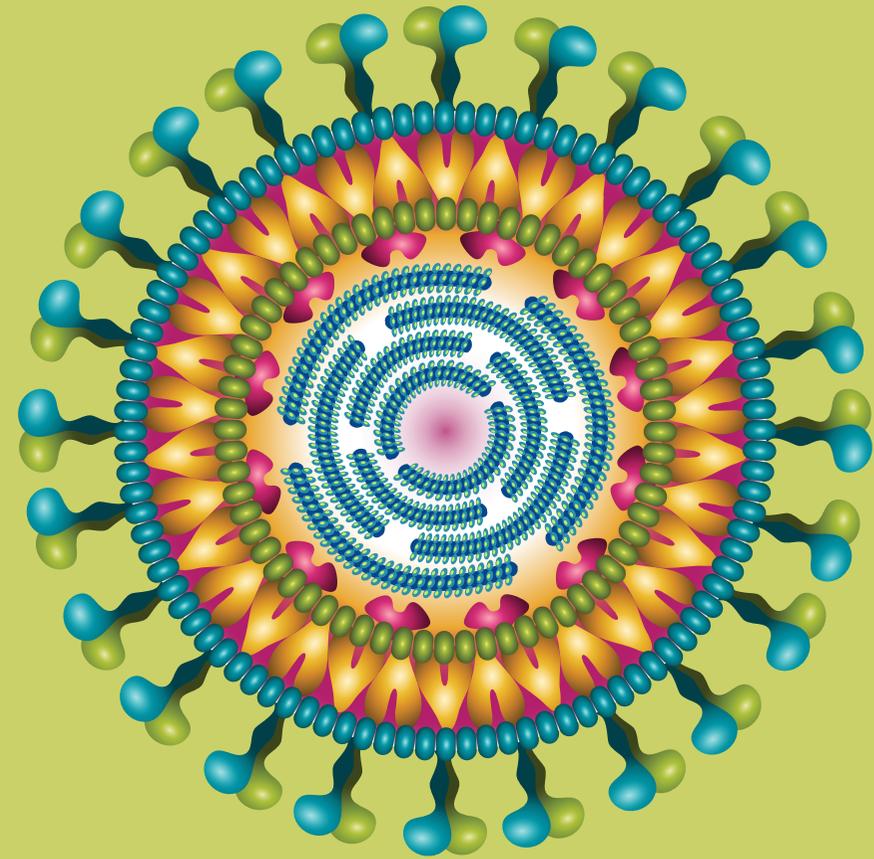
DISEASE

VIRUS

Rotavirus is the leading cause of severe diarrhoea among young children. Symptoms include profuse loose motions, vomiting, and fever. It can cause severe dehydration, and even death. Most infections occur in the very young, especially children under two years of age. Frequent vomiting makes it difficult to administer Oral Rehydration Solution (ORS) at home, and thus, requires hospitalization.

Rotavirus is a highly contagious virus that spreads rapidly from person to person through direct contact, contact through objects, respiratory droplets generated via sneezing, coughing or talking, or through the faeco-oral route. It can survive on hands and surfaces for long periods of time. Unlike other forms of diarrhoea, it cannot be prevented by basic hygiene alone. In both developing and developed countries, about 40 percent of hospitalized cases of infant diarrhoea are caused by Rotavirus. Rotavirus infections occur round the year in India, as opposed to Europe or the United States, where they are seasonal infections. Moreover, the Rotavirus strains occurring in India are far more diverse than anywhere else in the world.

The virus has been termed the “rota” virus owing to its wheel-like shape as visible under an electron microscope.



Schematic representation
of the Rotavirus



DISEASE BURDEN

In 2016, diarrhoea was the fifth major cause of global deaths in children under five years of age. Among these, Rotavirus accounted for the highest number of diarrhoea-induced deaths.

Before the introduction of Rotavirus vaccine, in 2013, India accounted for 22 percent of all under-5 Rotavirus deaths worldwide. The Indian National Rotavirus Surveillance Network has reported that Rotavirus is responsible for nearly 3.3 million outpatient visits, 0.88 million hospitalizations, and 78,000 deaths in India every year.

Rotavirus also poses a significant financial burden on families and the country. One study estimated that India spends about a hundred rupees per child in medical care for Rotavirus diarrhoea. The average cost of hospitalization for an episode of Rotavirus diarrhoea is about three thousand rupees, which is 7.6 percent of an average Indian family's total annual income. Thus, Rotavirus hospitalizations cost about US\$ 73 million each year, while outpatient treatments cost about US\$ 80 million in India.



“Bill Gates often tells the story of reading a newspaper article about the leading causes of childhood death, including Rotavirus. How is it possible, he wondered, that a disease that now kills 600,000 children per year is the focus of so little attention and investment?”

Dr Tachi Yamada, former president of the Foundation’s Global Health Programme

For Third World, Water Is Still a Deadly Drink

By NICHOLAS D. KRISTOF

THANE, India — Children like the Bhagwani boys scamper about barefoot on the narrow muddy paths that wind through the labyrinth of a slum here, squatting and relieving themselves as the need arises, as casual about the filth as the bedraggled rats that nose about in the raw sewage trickling beside the paths.

Parents, like Usha Bhagwani, a rail-thin 28-year-old housemaid, fret point out their children and fret about how to spend their rupees. Should they buy good food so that the children will get stronger? Or should they buy shoes so that the children will not get hookworms? Or should they send their sons and daughters to school? Or should they buy kerosene to boil the water?

There is not enough money for all of those needs, so parents must choose. It was to save money, as well as to save time, that Mrs. Bhagwani was serving unboiled water the other day to her 5- and 7-year-old boys in her one-room hov- el. Her boy face and sharp eyes softened as she watched them take the white plastic cup and gulp the deadly drink.

The water has already killed two of her children, a 15-month-old, Santosh, a boy who died two years ago, and Sheetal, a frail 7-month-old girl who died just a few months ago. But everyone in the slum drinks the water, usually without boiling, and water seems so natu- ral and nurturing that Mrs. Bhag- wani does not understand the men- ace it contains.

“I try to boil the water,” Mrs. Bhagwani said pleasantly. “But the boys sometimes insist on drinking right away because they’re thirsty.”

Then, she said, there is the cost.



Cambodian children get drinking water from creek used for bathing.

EVERYDAY KILLERS

Second of two articles

To boil water consistently would cost about \$4 a month in kerosene, almost a third of Mrs. Bhagwani’s earnings. She could afford that, but then there would be less money for food.

The water comes from a pipe that runs into the slum where the Bhagwanis live, in the city of Thane, near Bombay. The pipes are cracked and run in a ditch that is filled with sewage. Even if the water was properly treated at its origins, health workers say, sewage seeps into the water to produce one of the most deadly ailments in the world today: diarrhea. Diar-

rhea kills some 3.1 million people annually, almost all of them children.

The larger issue is that the most fundamental health challenge in the world at the end of the 20th century may be the same as it apparently was four millenniums ago: sanitation. To families like Mrs. Bhagwani’s, perhaps nothing would make more difference than clean water and a toilet.

All in all, human wastes may be more menacing than nuclear wastes, for feces kill far more people than radioactive substances. A range of diseases and parasites infect people by the fecal-oral route, transmitted from one per-

Continued on Page A8, Column 1



Bhagwani and her sons, left, don’t have enough money to pay for basic needs like food, shoes, schooling and kerosene to boil water. To save money, they often choose to drink water that has not been boiled. To the right, toilets clustered along the Mekong River in Phnom Penh, Cambodia. Billions of people in the third world don’t have access to even a decent pit latrine.



World’s Impoverished Lands, Water Is a Deadly Drink

A CLOSER LOOK

Death by Water

A huge range of diseases and parasites infect people because of contaminated water and food, and poor personal and domestic hygiene. Millions die, most of them children. Here are some of the deadliest water-related disorders.

DISORDER/ ESTIMATED DEATHS PER YEAR

DIARRHEA 3,100,000 Diarrhea is itself not a disease but is a symptom of an underlying problem, usually the result of ingesting

water that is contaminated with germs,” grumbled Jaya Pardi, a 25-year-old mother in Dharami. Her three small children were running around barefoot on a dirt pathway that they and all the other children also use as a toilet, and her 3-year-old daughter was sucking her filthy finger.

These urban slums present a sanitation nightmare. The challenge is increasing, because urbanization is a trend everywhere in the third world, from Brazil to Zambia. Villagers trek to cities and set up shacks on any bit of deserted ground, in places where there is no water and no toilet.

On the Bassac River just outside Phnom

Groups That Help Those Who Fall Ill

Readers have asked how to help victims of malaria and other diseases common in areas with poor sanitation and hygiene. Many organizations are active in combating these problems, including these:

Ativara, 441 R Street N.W., Washington, D.C.

DISCOVERY

In the 1980s, two serendipitous incidents occurred in separate medical facilities in India and triggered a nation-wide interest in the development of a new vaccine for children. An outbreak of diarrhoea in the neonatal ward of the All India Institute of Medical Sciences, New Delhi led Dr. MK Bhan to culture a stool sample of an infected neonate and discover an India-specific strain of Rotavirus. This particular Rotavirus strain was labelled as 116E.

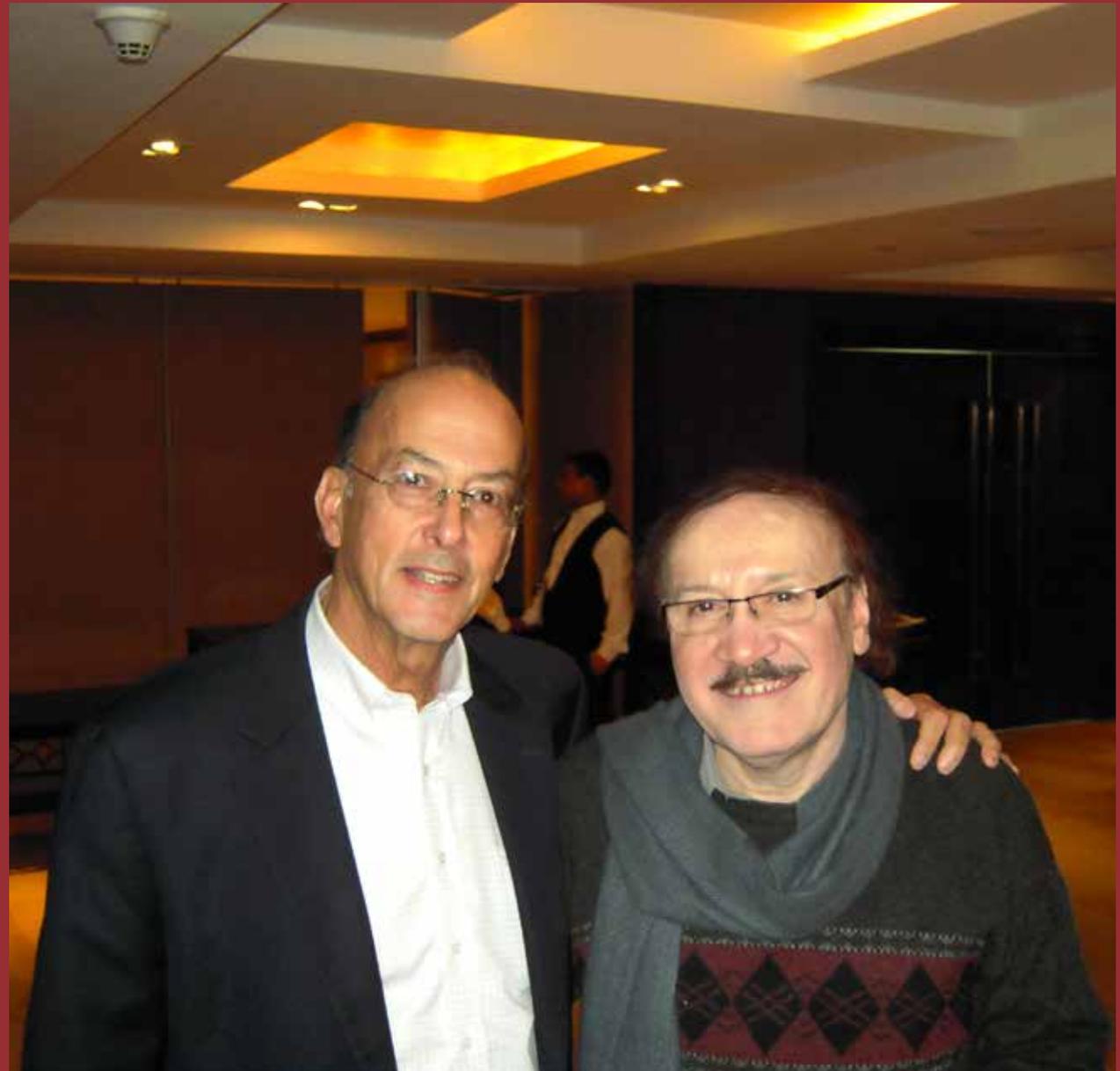
In another facility in Southern India, Dr. Durga Rao, at the Institute of Medical Science, Bengaluru, identified a different Rotavirus strain among neonates and named it the I321. While a change in the frequency of stools among the infants was observed, what piqued the curiosity of the doctors was the lack of any accompanying serious symptoms of diarrhoeal disease, such as vomiting and dehydration.

These observations compelled them to enquire whether infants continued to remain asymptomatic to repeated exposure of the pathogen. On subsequent exposure, the infected infants demonstrated a strong immune system response to the viruses without reporting any severe symptoms of diarrhoea. On further enquiry, it was discovered that both strains had undergone a process of natural-reassortment: an atypical mutation, which conferred the immune protection to the babies against the virus.



“ *In 1985, Dr. Maharaj Bhan and I met at a WHO meeting on diarrhoeal diseases in Calcutta. Dr. Bhan, then a young Assistant Professor of Pediatrics at the All India Institute of Medical Sciences (AIIMS), mentioned that he had been following an outbreak of Rotavirus in the newborn unit at AIIMS but noted surprisingly that the infected neonates did not develop diarrhoea. [...] These unusual but perceptive observations by Dr. Bhan led to our collaboration to characterize these neonatal Rotavirus strains [...] Most important is the prospect that this project could well lead to a novel vaccine for the prevention of Rotavirus diarrhoea in India and beyond.* ”

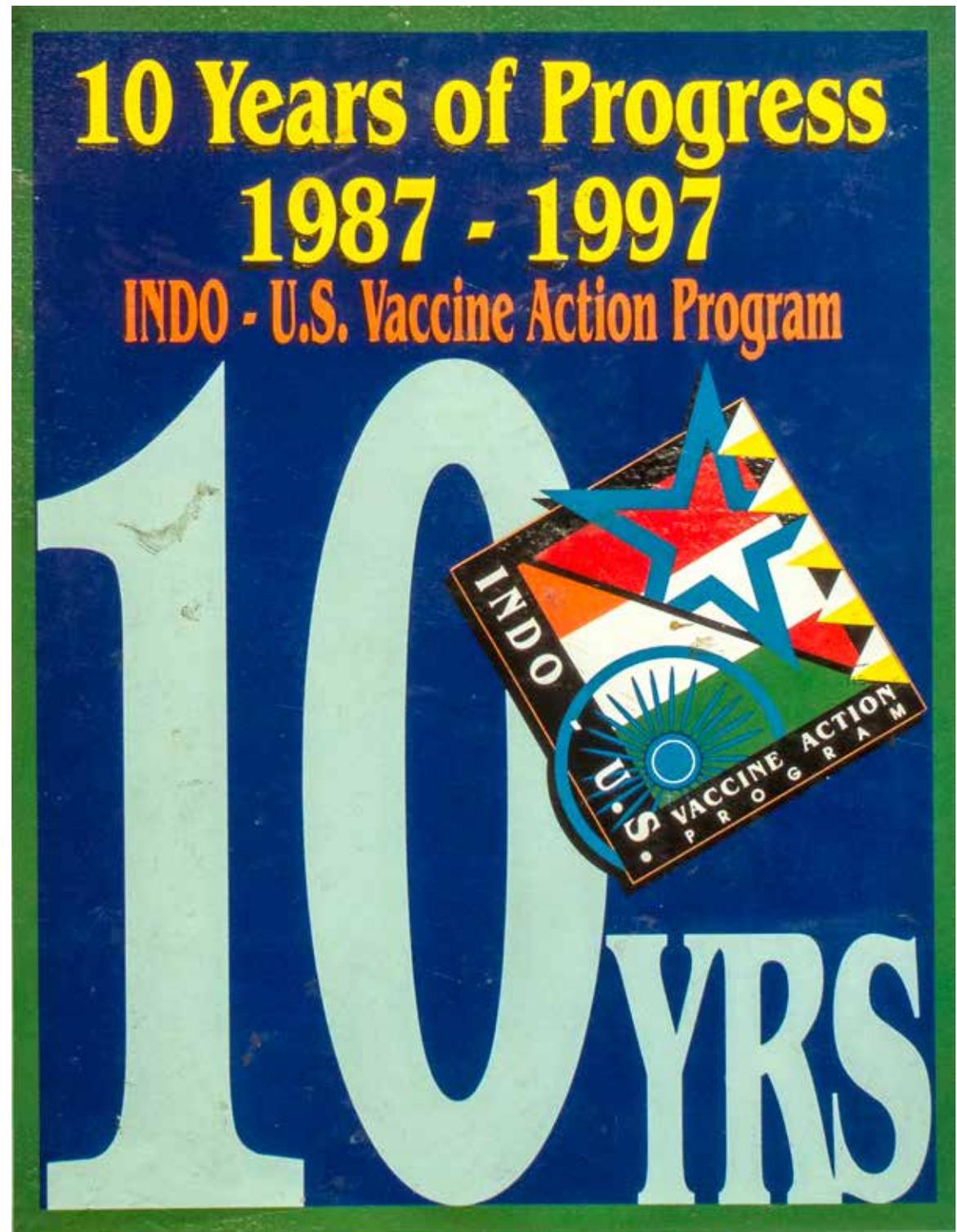
Dr. Roger I. Glass, Fogarty Director, NIH
on the Neonatal Rotavirus Vaccine Project
as a part of the 25th anniversary of
the Indo-U.S. Vaccine Action Programme



In the days following the discoveries, the two medical facilities, AIIMS and NIS, continued to engage in an informal collaborative study of the twin strains. After three years, the facilities developed a joint proposal to conduct further research, with an eye towards development of a vaccine.

The proposal was presented to the Indo-United States Vaccine Action Program - a bilateral programme, which supports vaccine related activities, including laboratory research, field trials, and delivery of vaccines - launched by the Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India; the National Institute of Allergy and Infectious Diseases and U.S. Department of Health and Human Services. The proposal was approved and, with funding from DBT, National Institute of Health (NIH), and USAID, further research on developing the vaccine commenced. This tireless endeavour, led by leading scientists and doctors across the country, lasted two decades.

In 1993, two pilot batches of the vaccines were tested on animals, adults and children in the United States. After testing safe across all three phases, the vaccine was transported to India. In 1998, the Indo-US VAP organized a meeting with potential vaccine manufacturers to proceed to the next stage of vaccine development.



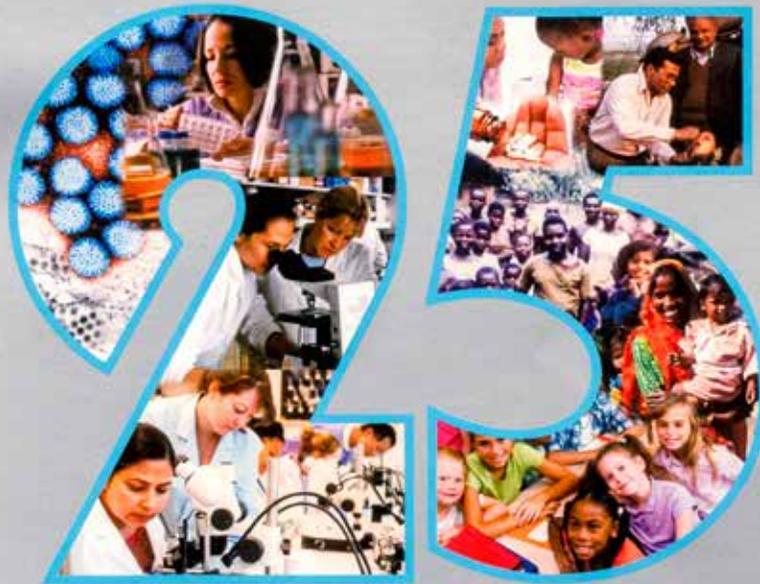
“Prime Minister Modi and President Obama reaffirmed their commitment to ensure that partnerships in science, technology and innovation are a crucial component of the overall bilateral engagement in the 21st century. [...] They also lauded the highly successful collaboration on a locally produced vaccine against Rotavirus which will save the lives of an estimated 80,000 children each year in India alone, and pledged to strengthen the cooperation in health research and capacity building through a new phase of the India-U.S. Vaccine Action Programme.”

Joint Statement during the visit of the President of USA to India - “Shared Effort; Progress for All”,
January 25, 2015



The First VAP JWG meeting in Action - Mr. S.C. Jain, Dr. S. Ramachandran, Secretary, DBT, Prof. A.S. Paintal Indian Co-Chairman, Prof. P.N. Tandon and Dr. Pushpa Bhargava.

INDO US | 25
 VACCINE ACTION PROGRAM | Years of Partnership



25 Years of Partnership, 1987 • 2012

Commemorative Silver Jubilee Publication
 September 3, 2012, New Delhi



Department of Biotechnology
 Ministry of Science & Technology, Govt. of India



National Institutes
 of Health



National Institute of
 Allergy and Infectious Diseases



Members of the Blue Ribbon Panel following their meeting with the Prime Minister, 1982

25 Years of Scientific Partnership 1987-2012

The Neonatal Rotavirus Vaccine Project Strain 116E - Rotavac

A Brief Review for the 25th Anniversary of the Indo-U.S. VAP

Article contributed by
Dr. Roger Glass
 Director, Fogarty International Center, NIH

In 1985, Dr. Bhan and I met at a WHO meeting on diarrheal diseases in Calcutta. We were lodged at a convent with strict rules so in the evening, we decided to go out for a drink, something not permitted on the premises. Dr. Bhan, then a young assistant professor of pediatrics at the All India Institute of Medical Sciences (AIIMS), mentioned that he had been following an outbreak of rotavirus (RV) in the newborn unit at AIIMS but noted surprisingly that the infected neonates did not develop diarrhea. (At the time, I was working in the lab of Dr. Al Kapikian at the National Institutes of Health (NIH) and we were characterizing an unusual group of rotaviruses collected from newborns on 4 continents that also did not cause disease. These unusual but perceptive observations by Dr. Bhan led to our collaboration to characterize these neonatal rotavirus strains and determine whether new

single VP4 gene segment replacement of bovine origin. The AIIMS strain, now called 116E, was characterized as genotype G9P10 that had not been seen previously.) Follow up of infected neonates by Dr. Jaysree Ayer at AIIMS indicated that these neonatal infants mounted a robust serum and mucosal immune response to rotavirus. Moreover, (study of a cohort of infected and non-infected infants by Drs. Bhan and Judy Lew (from CDC) indicated that those newborns infected were protected against subsequent severe rotavirus disease. This observation immediately raised the question of whether strain 116E might be a naturally attenuated candidate rotavirus vaccine.)

(Further studies of the epidemiology of rotavirus in India changed the way we think about the epidemiology of rotavirus infections in low vs. high income settings. In India, Drs. Madhu



Signing of the Vaccine Action Program Memorandum of Understanding - July 9, 1987 Founder/Secretary, Department of Biotechnology, Dr. S. Ramachandranand, U. S. Ambassador John Gunther Dean

DEVELOPMENT

ROTAVAC

Bharat Biotech International Ltd (BBIL), a Hyderabad-based start-up, was selected to take the Rotavirus vaccine-development forward. But they didn't have any previous experience in manufacturing a viral vaccine. Dr. Jon Gentsch from CDC and Dr. Harry B Greenberg from Stanford trained BBIL staff. The clinical development was co-funded by Department of Biotechnology, Government of India, Government of Norway and Bill & Melinda Gates Foundation through PATH.

However, hiccups came early on in the programme. Mycoplasma contamination of BBIL facility damaged the vaccine strain stock. It took more than two weeks and technical support from CDC to recover the vaccine virus and regrow them to a reasonably high titre, to rescue the development from a fatal collapse.

The pilot trials at National Institute of Health and then at the BBIL facility produced some encouraging results. Dr. Nita Bhandari and her team at Society for Applied Studies, continuing from their AIIMS work, demonstrated 116E strain to be safe and much more immunogenic than I321 strain. In parallel to this clinical development, with support from Dr. NK Ganguly, the then Director General ICMR, a Rotavirus surveillance effort was undertaken to map disease burden in five cities of India.

Even with this encouraging start, the protocol development for final phase 3 trials took two years, which started in March 2011 in three sites at SAS Delhi, KEM Pune and CMC Vellore. The vaccine was found to be highly efficacious and got licensed as Rotavac in 2015 in India and got pre-qualified by WHO in 2018. Rotavac became the first vaccine to be used without buffer, in a simple OPV like presentation, making it more compatible with the programme. Currently, Rotavac is being supplied to seven more countries beyond India.

Rotavac clinical trial team, 2011 ►







BBIL site visit by 116E project team

“This is an important scientific breakthrough against Rotavirus infections, the most severe and lethal cause of childhood diarrhoea, responsible for approximately 100,000 deaths of small children in India each year...”

**- K. Vijay Raghavan,
Secretary, Department of
Biotechnology, May 14, 2013**



Press Conference Rotavirus Vaccines for India The Evidence and the Promise



Department of Biotechnology
Government of India



INSTITUTES



Department of Biotechnology
Government of India

Press Conference

Rotavirus Vaccines For India
The Evidence and
The Promise



DR. SER. BHANU

DR. K. VEDAVYAGHIVAN

DR. KRISHNACHETTI

DR. Y.S. RAO



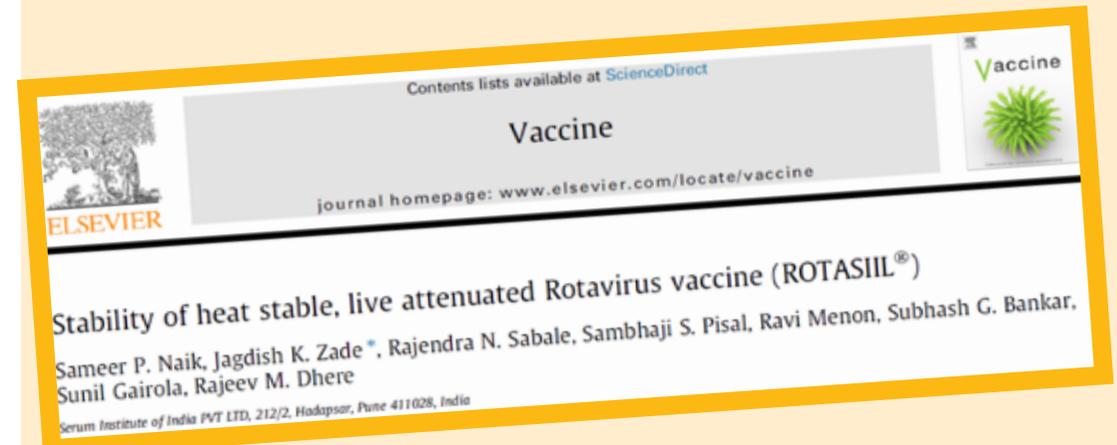
Dr. Harry B. Greenberg from Stanford, who mentored the BBIL team, is seen with THSTI colleagues

ROTASIIL

In 2017, India took another step in its fight against the deadly Rotavirus when Pune-based Serum Institute of India (SII) launched a new Rotavirus vaccine called the 'Rotasiil'.

Rotasiil is a heat-stable vaccine that does not require refrigeration. Thus, Rotasiil can be stored more conveniently in low-income countries where the probability of Rotavirus infection is most severe, and cold-chain systems are often ineffective or missing. PATH partnered with SII for testing the efficacy of Rotasiil in a Phase 3 national study with funding from Bill & Melinda Gates Foundation.

The study found no interference with the immune response to childhood vaccines when co-administered with ROTASIIL and confirmed the consistency of three different and independent lots of the vaccine produced by the SII. Rotasiil got WHO pre-qualification in 2018 and currently is being supplied to five more countries beyond India.





Serum Institute of India production facility for Rotasiil



The Rotasiil vaccine

“The Rotavirus vaccine helped prevent around 28,900 child deaths globally in 2016, but 100 percent vaccine coverage would have prevented a further 83,200 deaths. We need to work together to reach more people with this life-saving vaccine.”

Seth Berkley, CEO, Gavi



Rotasiil vaccine with diluent, adapter and oral syringes

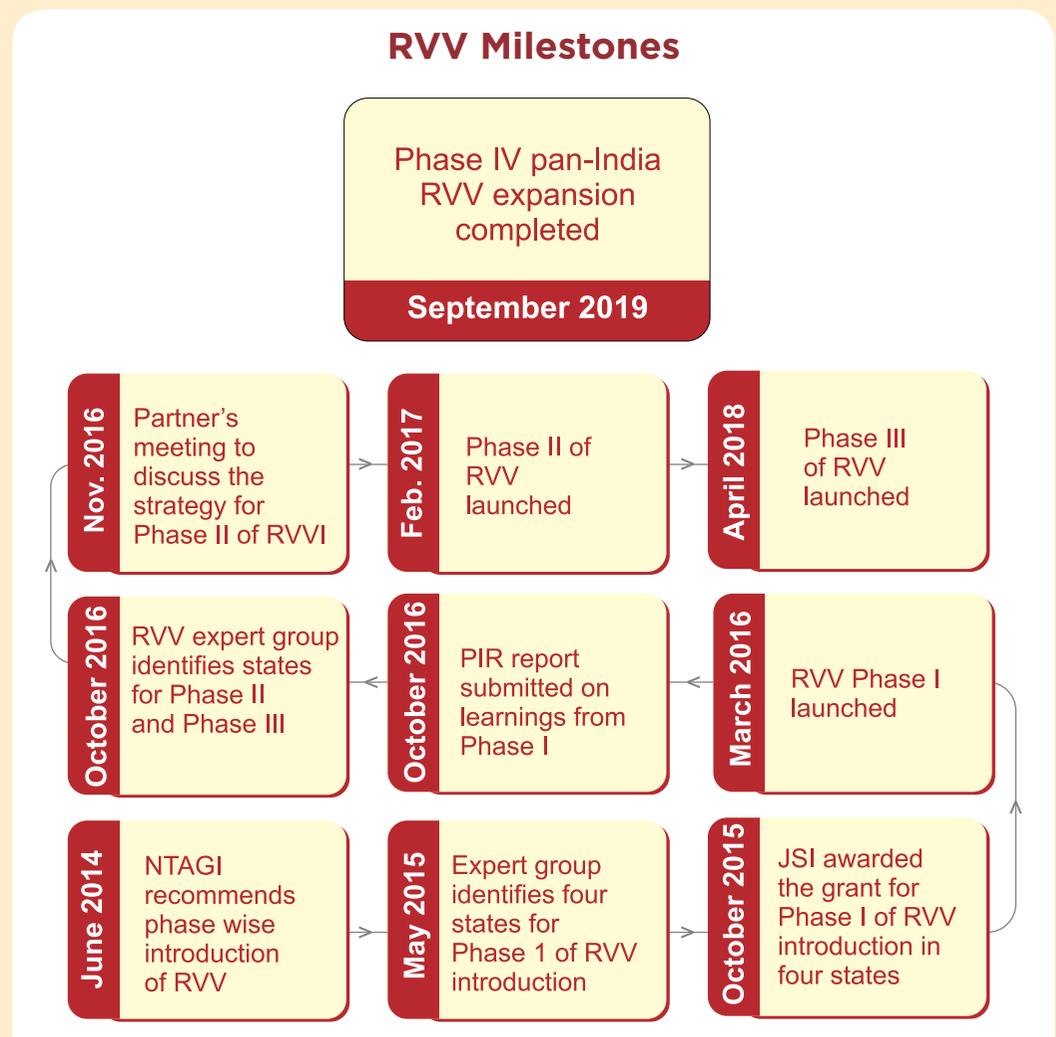
DECISION

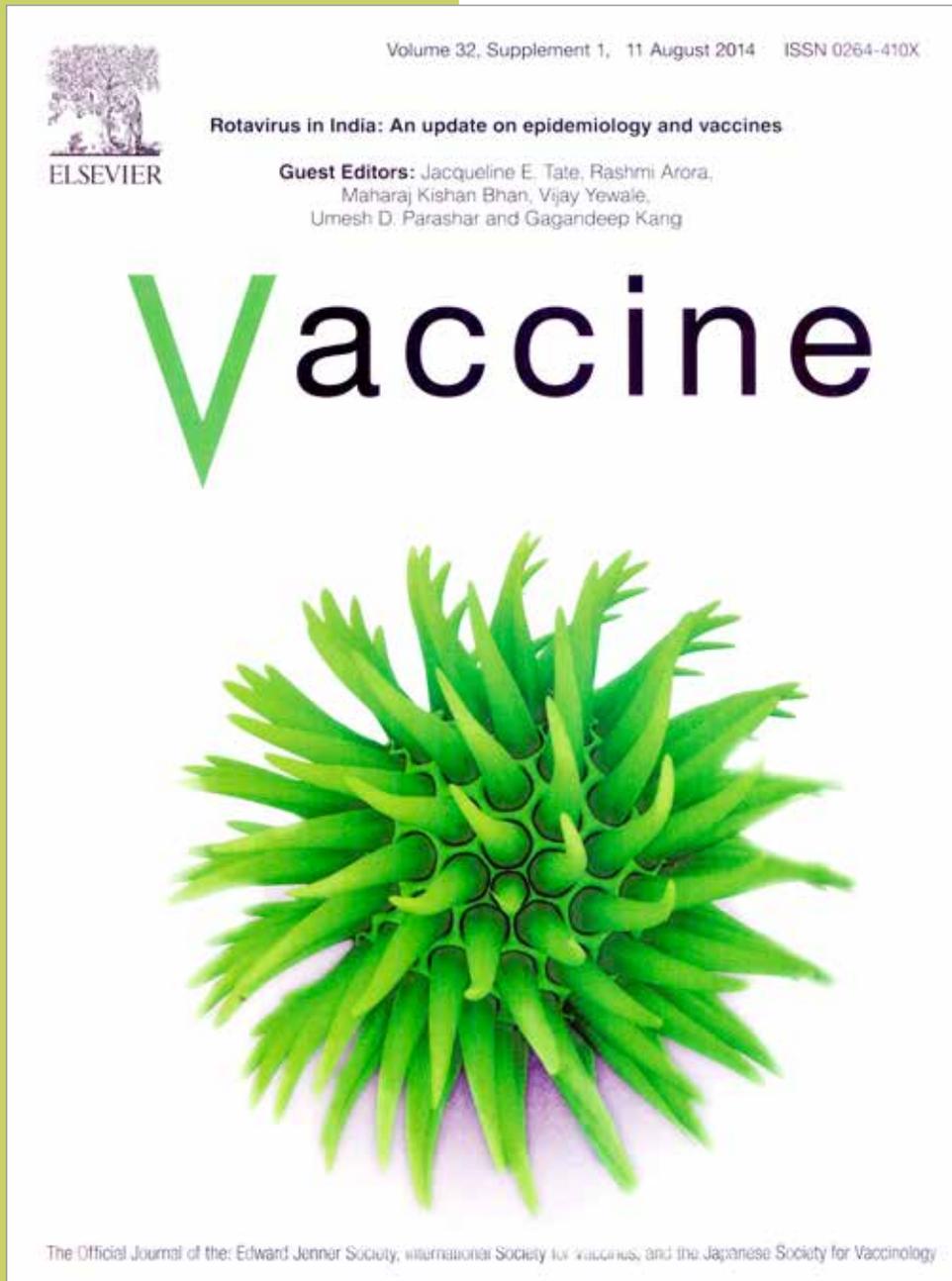
India followed an evidence-based process to assess the need and feasibility of Rotavirus vaccine introduction in the country. In a meeting held on June 16, 2008, the National Technical Advisory Group on Immunization (NTAGI) took cognizance of the development of the Rotavirus vaccine in the country, and constituted a Standing Technical Sub Committee (STSC) to assess the disease burden as well as review the available vaccine profile. Dr. Ambujam Nair Kapoor, from the Indian Council of Medical Research (ICMR) was appointed as the focal point to prepare all Rotavirus-vaccine related information.

Meanwhile, the Ministry of Health and Family Welfare, and the ICMR had already established the National Rotavirus Surveillance Network (NRSN) to estimate the burden of Rotavirus in under-five children, hospitalized for diarrhoea. By 2012, the NRSN added four referral and seven regional laboratories, and 28 clinical study sites in 19 states. Between September 2012 and December 2014, NRSN surveys detected Rotavirus in nearly 39.6 percent of 10,207 children hospitalized across the country. The Global Enteric Multicenter Study (GEMS) looked at the acute diarrhoea in children under five years of age at seven sites in Africa and Asia. The data from India site-National Institute of Cholera and Enteric Disease (NICED) showed that Rotavirus was the leading cause of diarrhoea in children under two years of age.

While the NRSN and GEMS established the Rotavirus disease burden in India, the NTAGI recommended a phased introduction of the Rotavirus vaccine in June 2014 based on the STSC deliberations on evidence for safety, efficacy, side effects, cost-effectiveness, and affordability of available Rotavirus vaccines, the programme capacity, and effectiveness of complementary measures of diarrhoea control in India. In November 2014 the Empowered Programme Committee endorsed the NTAGI recommendation followed by approval by Mission Steering Group in February 2015.

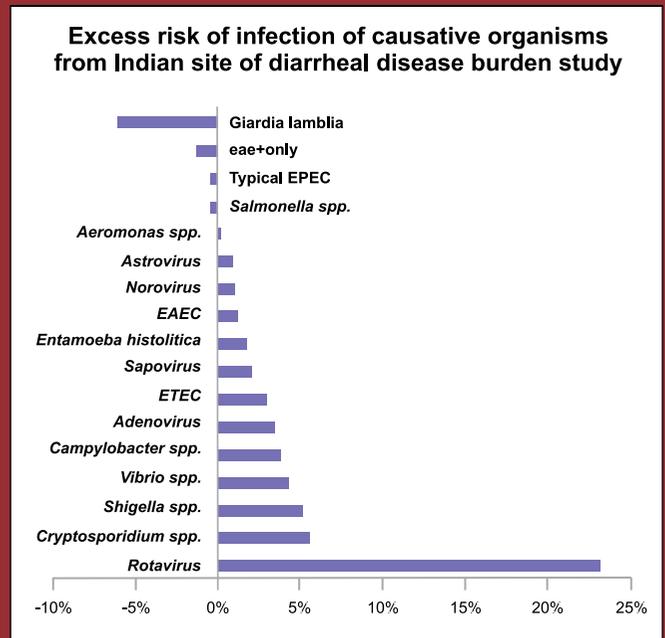
The National Technical Advisory Group of Experts (NTAGI) in its meeting held on June 12, 2014, recommended the use of Rotavirus vaccine in Universal Immunization Programme in phases, in parallel with evaluation of the results of post marketing surveillance and pilot observational study of 116E strain vaccine.





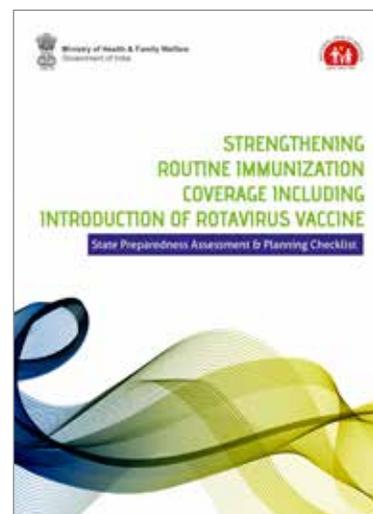
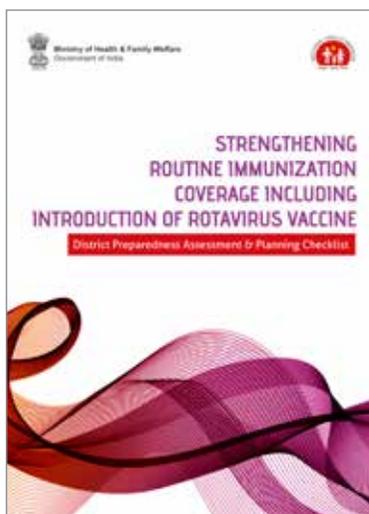
“Proper surveillance data is needed to convince policy makers and advocacy for the available and affordable vaccines.”

Dr. Dipika Sur, Lead Investigator, GEMS, India



DELIVERY PREPAREDNESS

Government of India constituted an expert committee under the Chairpersonship of Dr. NK Arora, INCLIN to provide guidance on selection of states for phased introduction. The committee also gave technical inputs on all training resources to be used for building capacity of the health workforce on Rotavirus vaccine implementation. State and district-level preparedness assessment checklists were developed and disseminated to allow programme managers to identify bottlenecks at the state, district and block levels for all programme components that required remedial action and prepare and implement a risk mitigation plan. The entire process is supported by all immunization partners including WHO, UNICEF, UNDP, JSI, NIHFV-NCCVMRC, INCLIN, GHS, PATH, CHAI and Bill & Melinda Gates Foundation under stewardship of immunization division, Government of India. JSI-ITSU coordinated with all partners and institutions on behalf of the ministry.



“The launch of Rotavirus vaccine in Jharkhand on April 7, 2018 by the Honourable Chief Minister is a major milestone in the efforts to reduce the under-five mortality. The vaccine has been introduced under the Universal Immunization Programme (UIP) and is being provided free of cost at all immunization sites across the state. The implementation is being monitored at the highest level. JSI along with all other immunization partners are actively supporting the state in this introduction.”

Ms Nidhi Khare, IAS, Principal Secretary-Health, Jharkhand, India

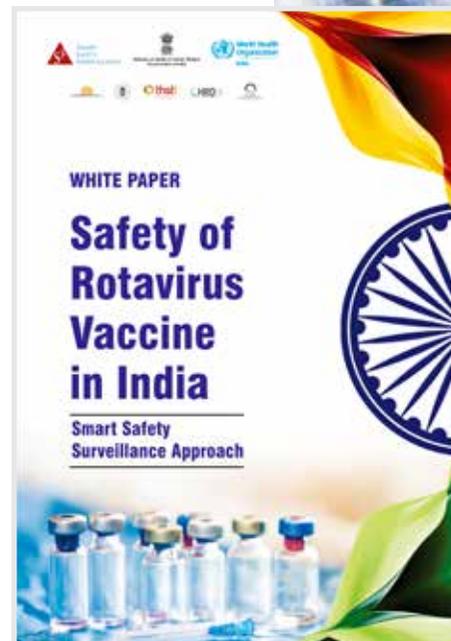


“We utilized the New Vaccine Introduction (NVI) opportunity in overall strengthening of RI programme of state. The experiences from RVVI were very much beneficial for state which were also used in Pneumococcal Conjugate Vaccine introduction in 2017. The hurdles and challenges were identified and planned actions were taken.”

Dr. Mangla Sood, State EPI Officer, Himachal Pradesh, India

SAFETY SURVEILLANCE

Rotavirus vaccine comes with the concern of a rare adverse event-intussusception. The Government of India recognized the harmful potential of said concerns to delay and derail the introduction of the vaccine in the country at the earliest stage of policy deliberations. Accordingly, three large safety studies have been commissioned to generate evidence on the safety of the Indian vaccines to be used in the country. Recently, a white paper was published compiling all safety data from the following sources; i) Periodic Safety Update Reports submitted to CDSCO by the manufacturer; ii) cases reported to and analyzed by Adverse Events Following Immunization Secretariat [Immunization Division], iii) an early roll out study recommended by the National Technical Advisory Group on Immunization and conducted by the Centre for Health Research and Development, Society for Applied Studies and partners, and; iv) thirty two sentinel sites established as recommended by WHO for post-marketing surveillance of Rotavirus vaccines by the Translational Health Sciences & Technology Institute (Department of Biotechnology, Ministry of Science & Technology). There has also been a retrospective and prospective intussusception study at seventeen sites by INCLIN. Collectively, over 1,500 intussusception cases have been analysed but none of these studies has identified any risk of intussusception following administration of Rotavac vaccine in the country. This coordinated effort by the research institutions and programme partners will strengthen national pharmacovigilance systems that support regulatory decisions for all vaccines throughout their lifecycle.



SAFETY: FIELD STORY

AEFI management kits in Tamil Nadu

In order to manage the AEFIs, especially serious AEFIs, it is essential to have a fully stocked AEFI management kit in every health facility. To ensure that these drugs are readily available to the health care functionaries, the Government of Tamil Nadu has developed a mechanism for providing their staff with all the essential drugs for management of AEFI in a brief case with dosage and schedule of the drugs pasted on it. This kit is easy to carry and all drugs are well arranged which ensures that any drug is readily available in case of emergency.



AEFI Management Kit



National AEFI committee experts (including Dr. MK Agarwal, Dr. NK Arora and Dr. Satinder Aneja) assessing causality of AEFI cases (May, 2016)



Training of trainers for safety surveillance project conducted by CHRD/SAS/INCLIN at Pune, 2015.

SUPPLY CHAIN

The Rotavirus vaccine introduction acts as a catalyst for the strengthening of the immunization supply chain. Before the introduction of Rotavirus vaccine, a cold chain space assessment is done to identify space constraints at each cold chain point in every state and district. The cold chain space in the identified, deficient cold chain points are then augmented through repair of existing equipment, rationalization of available inventory and procurement of new equipment. Between 2016 and 2019, Government of India has procured more than 25,000 electrical cold chain equipment to add more than 1.8 million liters of ILR space (2 to 8 degree centigrade) and more than 1.2 million liters of deep freezer (-15 to -25 degree centigrade) space. The electronic vaccine intelligence network (eVIN), a mobile based real time supply chain data solution, being operational in more than 20,000 cold chain points in 21 states, ensured Rotavirus vaccine availability at every session in an efficient way.



Walk-in-cooler and dry storage at Aurangabad, Bihar

Dr. Duncan Steele and Dr. Arindam Ray from Bill & Melinda Gates Foundation learning about Rotasiil storage process at Jharkhand, September 2018





आपको दैनिकी नुस्खा खाने एवं खाना जल्द से खाना के
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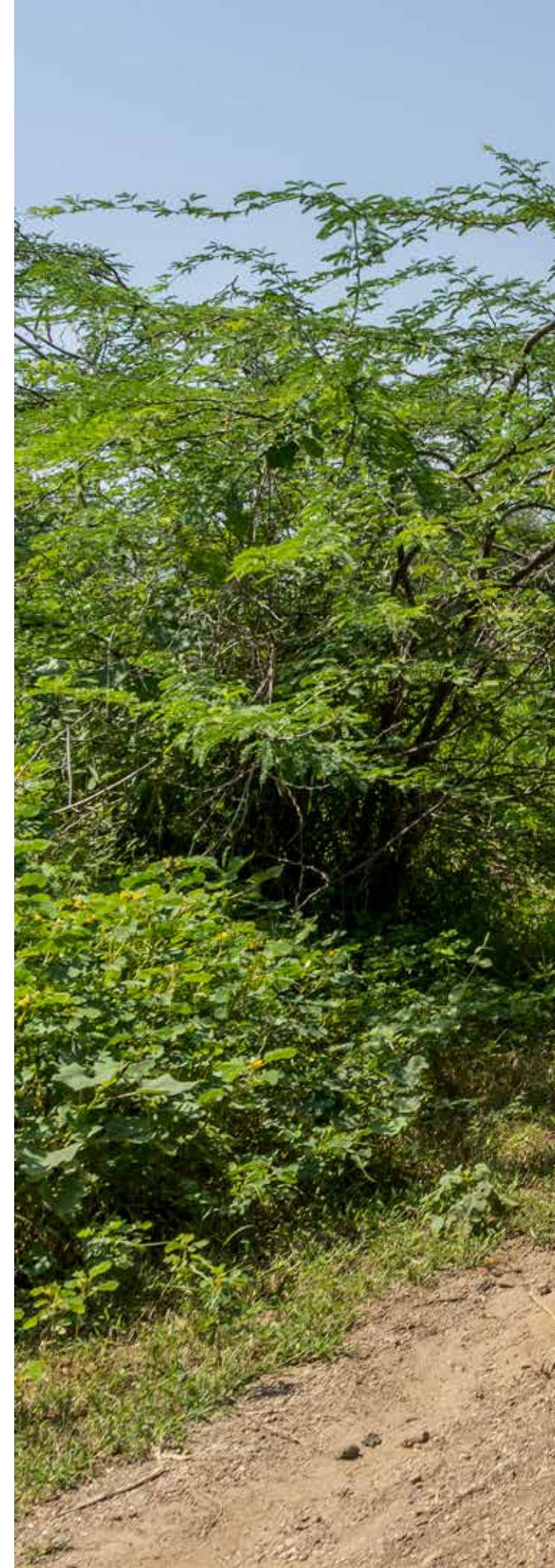
SUPPLY CHAIN: FIELD STORY

Mohit Singh has been working as the State Vaccine Logistics Manager for the last seven years at state vaccine store, Ranchi. He is responsible for handling the distribution of vaccines and logistics for all vaccines under the UIP. He carries a huge responsibility of ensuring that vaccines and logistics are available at every session site in Jharkhand every week.

“When I first got the letter from MoHFW that a new type of RVV will be supplied for introduction in Jharkhand, I was initially anxious about the availability of additional cold chain space and also the challenge of ensuring that the diluent along with the required logistics namely oral syringe and adapter are available at all sessions. However, the extensive training and technical support from the state programme managers enabled me to overcome all apprehensions and ensure that the supply chain is streamlined for ensuring 100 percent vaccine availability.”



State vaccine store, Ranchi, Jharkhand





*Alternate Vaccine Delivery (AVD)
person is carrying vaccine carriers to a
session site at Barwani district, Madhya
Pradesh, September 2018*



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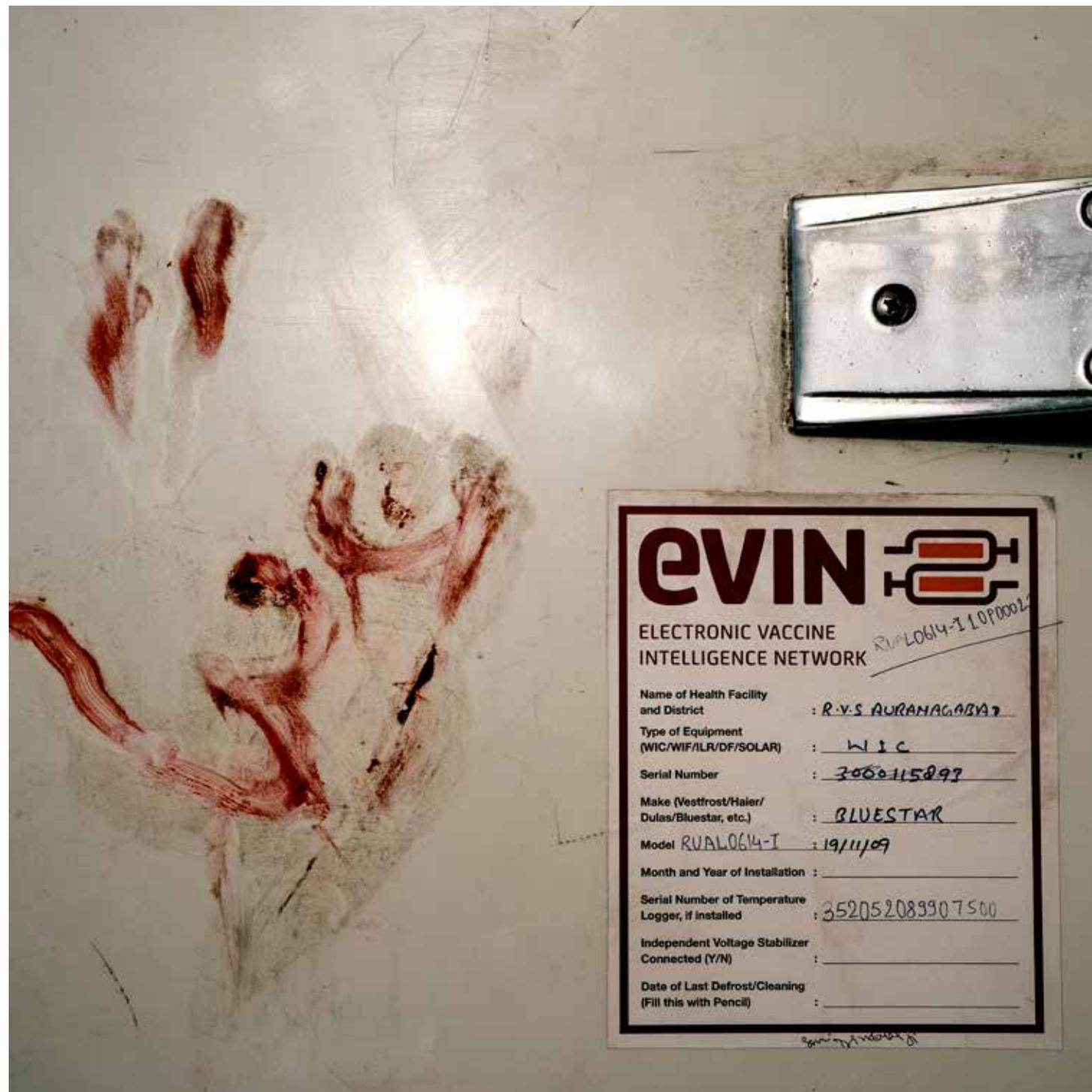
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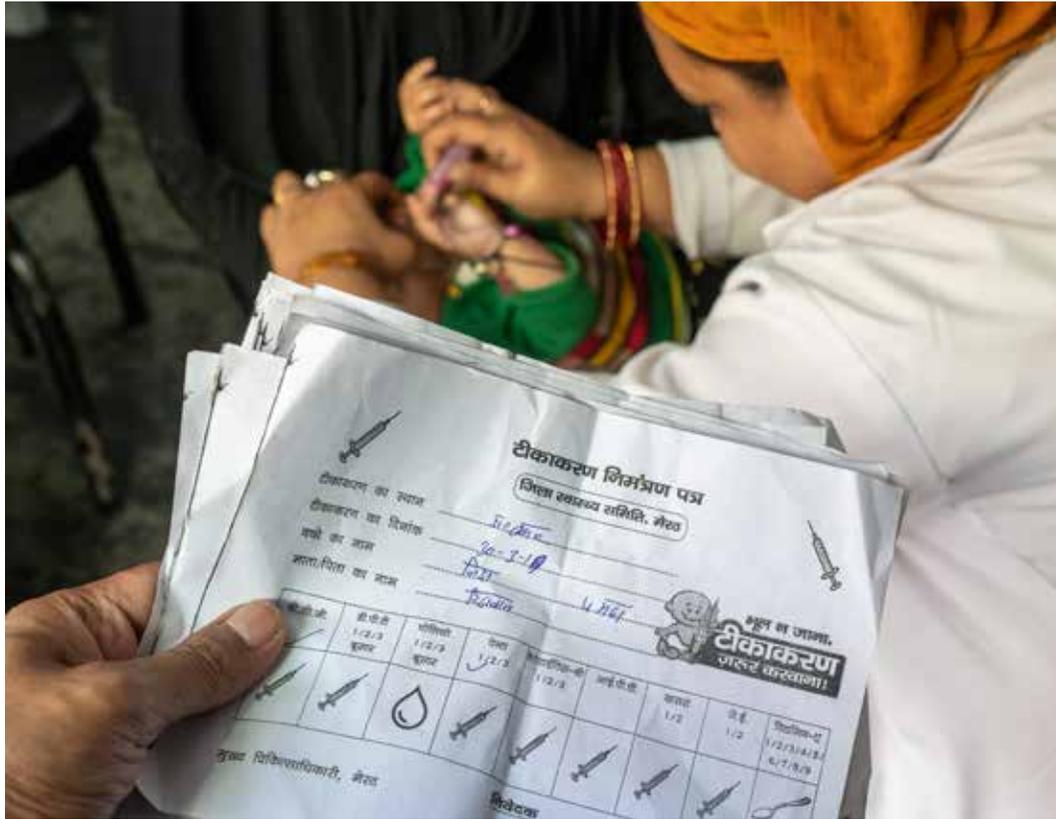


eVIN is a game changing solution supported by Gavi HSS to bring real time visibility to cold chain inventory, vaccine stock & flow and temperature excursions, which has helped India to eliminate stock-outs and ensure vaccine availability at last mile

Left: Vaccine carriers

RECORDS AND REPORTS

Every new vaccine introduction necessitates a revision in the recording and reporting formats, both the paper based and also the online ones. The introduction of Rotavirus vaccine in the programme also led to updation of the due list cum tally sheet, monthly progress reports, vaccine stock and distribution registers, RCH register, MCP card and other state specific tools. The online tools like the HMIS, RCH portal, eVIN, ANMOL and others were also updated. This revision in the recording and reporting tools is essential to capture consumption and coverage data which can then be triangulated with the concurrent monitoring data for effective analysis of programme implementation.



दिनांक	स्थान	कुल स्टॉक	उपलब्ध स्टॉक	वैसीन का प्रकार	वैसीन का मात्रा	वैसीन का मूल्य	वैसीन का मूल्य	वैसीन का मूल्य	वैसीन का मूल्य
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Recording and reporting tools



Programme Implementation Review and field monitoring of Rotavirus vaccine introduction, Jharkhand

TRAINING

A four-tier cascade training model is followed, wherein respective health representatives are trained at the national level followed by trainings at state, district and block levels. The trainings are customized to the two vaccines, the Rotavac and the Rotasiil, used under the programme. Immunization experts from fourteen partner organizations, along with the government counterparts trained about 5,000 master trainers who in turn trained more than 43,700 medical officers, ~28,000 cold chain handlers, ~275,000 ANMs, ~886,000 ASHAs and ~10,00,000 AWWs, in about 11,000 training sessions. Senior central government officials and partners supports the states and districts in planning the trainings, sensitizing the health officials, and monitoring the quality of session delivery. Innovative adult learning approaches are followed, including a “station approach” for intense small group interactive, hands-on learning.



Rotavirus vaccine training in Budgam, Srinagar, Jammu & Kashmir

Dr. Pradeep Haldar, Advisor (RCH), MoHFW, Government of India at Guwahati training session, April 2019



WORKSHOP FOR
VACCINE
INTRODUCTION
ASSAM, BIHAR, JHARKHAND,
KARNATAKA, KERALA,
MIZORAM, NAGALAND,
ODISHA, WEST BENGAL
2019



Dr Veena Dhawan



Dr Jay



Dr Debashish Roy

REGIONAL WORKSHOP FOR
ROTAVIRUS VACCINE
INTRODUCTION
ASSAM, BIHAR, JHARKHAND,
KARNATAKA, KERALA,
MIZORAM, NAGALAND,
ODISHA, WEST BENGAL
April 2019
Gurugram



RVV training session at Hyderabad, May 2019



RVV training session in West Bengal, July 2019

there is no alternative to Rotavirus Vaccine?

240

Diarrhoea

Countries



Developing Countries



Rotavirus related diarrhoea

1. Rotavirus diarrhoea is common in both developed and developing countries
2. Rotavirus cannot be eliminated by improving sanitation and hygiene only. The virus spreads through fomites as well as person to person contact
3. ORS and zinc should be continued to prevent the severity of infection
4. Rotavirus diarrhoea is more prevalent during 3-4 months of age. Incubation period is 1 - 3 days
5. Rotavirus diarrhoea is more prevalent during the winter season. Diarrhoea and vomiting are the most common symptoms
6. Re-infection is not uncommon. However, subsequent infections are less severe



Ministry of Health
& Family Welfare
Government of India

Introduction of Rotavirus Vaccine in the
Universal Immunization Programme
Frequently Asked Questions
For Medical Officers



Given Orally 2.5 ml dose





Hands-on training on Rotasiil administration, May 2019

◀ *RVV training session for medical officers, July 2019*



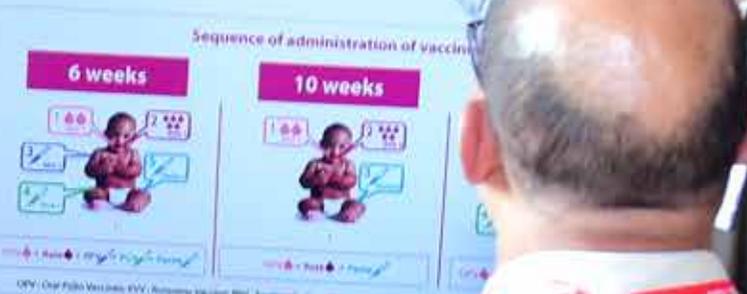
*Dr. Pradeep Haldar and Dr. Raj Shankar Ghosh
in a RVV district workshop, July 2019*

*Dr. Subhasis Bhandari
facilitating a RVV training session
through station approach, April 2019*



National Immunization Schedule (after introduction of Rotavirus vaccine)

Age	Vaccines given	Notes
At birth	BCG, OPV-0, HepB first dose	Rotavirus vaccine is a live attenuated, oral (liquid) vaccine
6 weeks	OPV-1, BUV-1, DTP-1, Polio-1, Pentavalent-1	It is given in a 5 dose vial
10 weeks	OPV-2, BUV-2, DTP-2, Polio-2, Pentavalent-2	The vaccine pack for 5 dose vial contains 25 doses of 2.5 drops
14 weeks	OPV-3, BUV-3, DTP-3, Polio-3, Pentavalent-3	Each vaccine vial is supplied with a pink coloured dropper
9 months	MM-1, Hib-1	VVM is on the cap of the vaccine vial
16-24 months	MM-2, Hib-2	
5-6 years	MM-3, Hib-3	
10 years	MM-4, Hib-4	
16 years	MM-5, Hib-5	



- Each dose of the vaccine is 5 drops (0.5ml) to be administered in the vaccine.
- Three doses of rotavirus vaccine will be administered along with other vaccine in routine immunization.
- No booster dose of Rotavirus vaccine is given.

National Immunization Schedule (after introduction of Rotavirus vaccine)

Age	Vaccines given	Notes
At birth	BBC, OPV-0, HepB first dose	Rotavirus vaccine is a live attenuated, oral (liquid) vaccine
6 weeks	OPV-1, BUV-1, DTP-1, Polio-1, Pentavalent-1	It is given in a 5 dose vial
10 weeks	OPV-2, BUV-2, DTP-2, Polio-2, Pentavalent-2	The vaccine pack for 5 dose vial contains 25 doses of 2.5 drops
14 weeks	OPV-3, BUV-3, DTP-3, Polio-3, Pentavalent-3	Each vaccine vial is supplied with a pink coloured dropper
9 months	MM-1, Hib-1	VVM is on the cap of the vaccine vial
16-24 months	MM-2, Hib-2	
5-6 years	MM-3, Hib-3	
10 years	MM-4, Hib-4	
16 years	MM-5, Hib-5	

INTRODUCTION

Rotavirus Vaccine
Introduction

टीके लगाने पर सरकार...
धान सचिव ने फुलवारी से रोटा वायरस टीके को कि



बच्चों को रोटा वायरस टीके के लिए रोटा वायरस टीके को निर्धारित प्रारंभिक आयु में ही देना चाहिए। स्वास्थ्य विभाग के सचिव ने बताया कि रोटा वायरस टीके को 6 माह से 5 वर्ष की आयु तक के बच्चों को देना चाहिए। इस टीके को सभी बच्चों को देना चाहिए।

Rotavirus vaccine to be administered in UT

HT Correspondent
chandigarh@industianimes.com

CHANDIGARH: The health department, Chandigarh, is going to introduce a rotavirus vaccine (RVV) in its routine immunisation schedule from July onwards.

Rotavirus vaccine will be provided free of cost under the Universal Immunisation Programme (UIP). Rotavirus is a highly contagious virus causing diseases in babies and young children. Vaccination is the only specific intervention strategy for protection from rotavirus infection.

The rotavirus vaccine has been rolled out in 11 states across the country in a phased manner and now, is being expanded to the remaining 25 states and union territories including Chandigarh. It is given orally to infants in a three-dose schedule at 6, 10 and 14 weeks of age. The vaccine will be co-administered with other vaccines as per the

The vaccine protects 9 out of 10 children from getting severe disease caused by the virus. Rotavirus accounts for 40% of diarrhoea in children. Other features of rotavirus infection include dehydration, electrolyte imbalance, shock, and death. The rotavirus vaccine has been included in the National Immunisation Programme of 96 countries.

रोटा वायरस कार्यशा



संयुक्त स्वास्थ्य विभाग के सचिव ने बताया कि रोटा वायरस टीके को 6 माह से 5 वर्ष की आयु तक के बच्चों को देना चाहिए। इस टीके को सभी बच्चों को देना चाहिए।

उपलब्धि: रोटा वायरस टीकाकरण में उत्तराखण्ड भी शामिल

भारत सरकार स्वास्थ्य एवं परिवार कल्याण विभाग के अधिकारी दे रहे प्रशिक्षण।

उत्तराखण्ड में रोटा वायरस टीकाकरण शुरू करने के लिए स्वास्थ्य विभाग के अधिकारी प्रशिक्षण दे रहे हैं।



बच्चों को लगाई जाएगी रोटावायरस वैक्सीन।

दैनिक भास्कर 09-Jun-2019 जशपुर Page 3

दैनिक भास्कर

स्वास्थ्य • बीएमओ, बीपीएम एवं मितानिनों को दी गई टीकाकरण को लेकर ट्रेनिंग जुलाई में बच्चों को लगेगा रोटा वायरस का टीका

उत्तराखण्ड में रोटा वायरस टीकाकरण शुरू करने के लिए स्वास्थ्य विभाग के अधिकारी प्रशिक्षण दे रहे हैं।

गी रोटावायरस वैक्सीन की बूट



टीके के साथ 6 साप्ताह, 10 साप्ताह और 14 साप्ताह की उम्र से बच्चों को रोटावायरस वैक्सीन की 5-5 बूटें दी जाएंगी।

रुटा वायरस का टीका नहीं लगाने से हो सकती है पेट की गंभीर बीमारी

जुलाई से चलेगा अभियान, दी गई अधिकारी-कर्मचारियों को ट्रेनिंग।

रोटावायरस वैक्सीन

रोटा वायरस टीकाकरण की दी गई विस्तृत जानकारी।

रोटा वाइरस वैक्सीन

2019 देहरादून जागरण।

टीकाकरण में शामिल होगी रोटा वायरस वैक्सीन

अभी तक देश के 11 राज्यों में ही है व्यवस्था।

Rotavirus vaccine launched in city

Prevents diarrhoea in infants & children.

रोटा वायरस टीकाकरण की दी गई विस्तृत जानकारी

मामो-बीपीएम सहित मेडिकल स्टाफ प्रशिक्षित।

भ्रस्पतालों में मुफ्त यरस वैक्सीन

2000 रुपये तक किए जाते हैं चार्ज।

रोटा वायरस से बचाव को शुरू हुआ टीकाकरण

टीकाकरण शुरू किया टीकाकरण।

Rotavirus vaccine being administered to a child in Chandigarh.

CHANDIGARH, JULY 31: The Health Department today launched rotavirus vaccine in infants and children in the city.

पत्रिका... 52

भ्रस्पतालों में मुफ्त यरस वैक्सीन 2000 रुपये तक किए जाते हैं चार्ज।

टीकाकरण शुरू किया टीकाकरण।

Rotavirus vaccine being administered to a child in Chandigarh.

Dr. SN Bagchi supervising the demo administration of Rotasiiil vaccine by an ANM



COMMUNICATION

As part of the integrated communication strategy, a 360 degree approach is taken to highlight the need, value and safety of the Rotavirus vaccine, using both electronic and print medium, including banners, posters, leaflets, audio-visuals and radio jingles. These were developed in fourteen regional languages. Mass and mid media were extensively used for informing the community of the benefits of Rotavirus vaccine as the specific intervention to prevent Rotavirus diarrhoea within the holistic health messaging of diarrhoea control including hand washing.

Media sensitization workshops were organized, and state specific media kits were distributed, prior to the launch of the vaccines. The trainings and launch of the programme were extensively covered in national and regional print, electronic and social media helping adoption of the vaccine in the community.

Separate training material packages were designed for every cadre and relevant guidelines, leaflets, were disseminated to introduce trainees to the Rotavirus Vaccine. The IEC promotional material was printed in 14 regional languages.

Immunization awareness as a part of gender and health literacy initiative, Bihar





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98.3 FM

98.3 FM

98.3 FM

98.3 FM

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क्याँ वही लिली

क्याँ वही लिली



RVV banner, Itanagar, Arunachal Pradesh



Immunization umbrellas with Rotavirus message in Madhya Pradesh



Teeku-talk as a part of the public advocacy initiative for routine immunization, Bihar



रखें अपने बच्चे के अगले
टीके की तारीख याद
टीकू टॉक

टीकाकरण
टीकू टॉक
टीकाकरण के बाद
रुकें नहीं, खेलें बसो
टीकाकरण के बारे में जानें-टीकाकरण के लिए यह सही वक्त है

बाहर पड़े अगर जाना
टीकाकरण कार्ड साथ ले जाना
टीकू टॉक

5 साल 7 बार,
छूटे ना टीका एक भी बार
टीकू टॉक

टीकाकरण के बाद
रुकें नहीं, खेलें बसो

COMMUNICATION: FIELD STORY

Manubankul is a hard-to-reach and far-flung block in South Tripura District of Tripura State, India. The total population of the block is 35,000. The residents are predominantly from Chakma, Mog and Barua communities who are followers of Buddhism. Ven. Dr. Dhammapiya is the religious head of the community and their preacher.

Legend has it that the king of the Mog community was killed by a rival a thousand years back. The folklore says that the king will be reborn to a woman of the community and the baby's birth is awaited by all. The Mog community believes that vaccinating this child may even lead to the death of the reincarnated king and therefore they do not allow vaccination of any beneficiary. As a result, this Primary Health Centre has dismal immunization coverage.

When Rota virus vaccination was introduced in Tripura in 2017, the community vehemently refused to accept the vaccine. The Chief Medical Officer, Dr. Jagadish Nama and his team, along with Dr. Saumendra Nath Bagchi from JSI and Dr. Anjan Chattaraj from WHO, met with Dhammapiya. The team explained the benefits of Rota virus vaccine and convinced him to talk to his community members. Dhammapiya got persuaded and he took the initiative to guide the Mog community who accepted his advice and agreed to have the children vaccinated.

This is a perfect example of how the programme can engage with the spiritual/religious leaders, who are the strong influencers in Indian society to build community trust in the vaccines.



Ven. Dr. Dhammapiya is the religious head of the Chakma, Mog and Barua communities and their preacher





Training materials in various regional languages

COMMUNICATION: FIELD STORY

Immunization Umbrella (Suraksha Chhatri) in Madhya Pradesh



Government of Madhya Pradesh developed and provided rainbow coloured “Immunization Umbrella” also called as “Suraksha Chhatri” to mobilizers (ASHA & AWW) during the Intensified Mission Indradhanush (IMI) campaign. This was part of an initiative by the state government to create community awareness on immunization and also at the same time enable the mobilizers to protect themselves from the sun and the rain. The clubbing of RVV with Pentavalent vaccine in the same colour reinforced the message that both the vaccines need to be given at the same visit following similar schedule.

Rotavirus vaccine Information, Education and Communication (IEC) on vaccine carriers in Madhya Pradesh

Display of IEC material is one of the core mechanism for bringing awareness among the community. Mostly IEC material were developed and displayed in form of banners, posters and wall paintings at the health facilities, village walls for generating awareness.

Health authorities of Jabalpur district in Madhya Pradesh went a step ahead and developed immunization stickers with focus on Rotavirus vaccine which were pasted on vaccine carriers used for transportation of vaccines to the last mile. This not only helped in spreading the message of Rotavirus vaccine among the community but also worked as a remembrance tool for ANMs regarding dosage and schedule of the new vaccine.

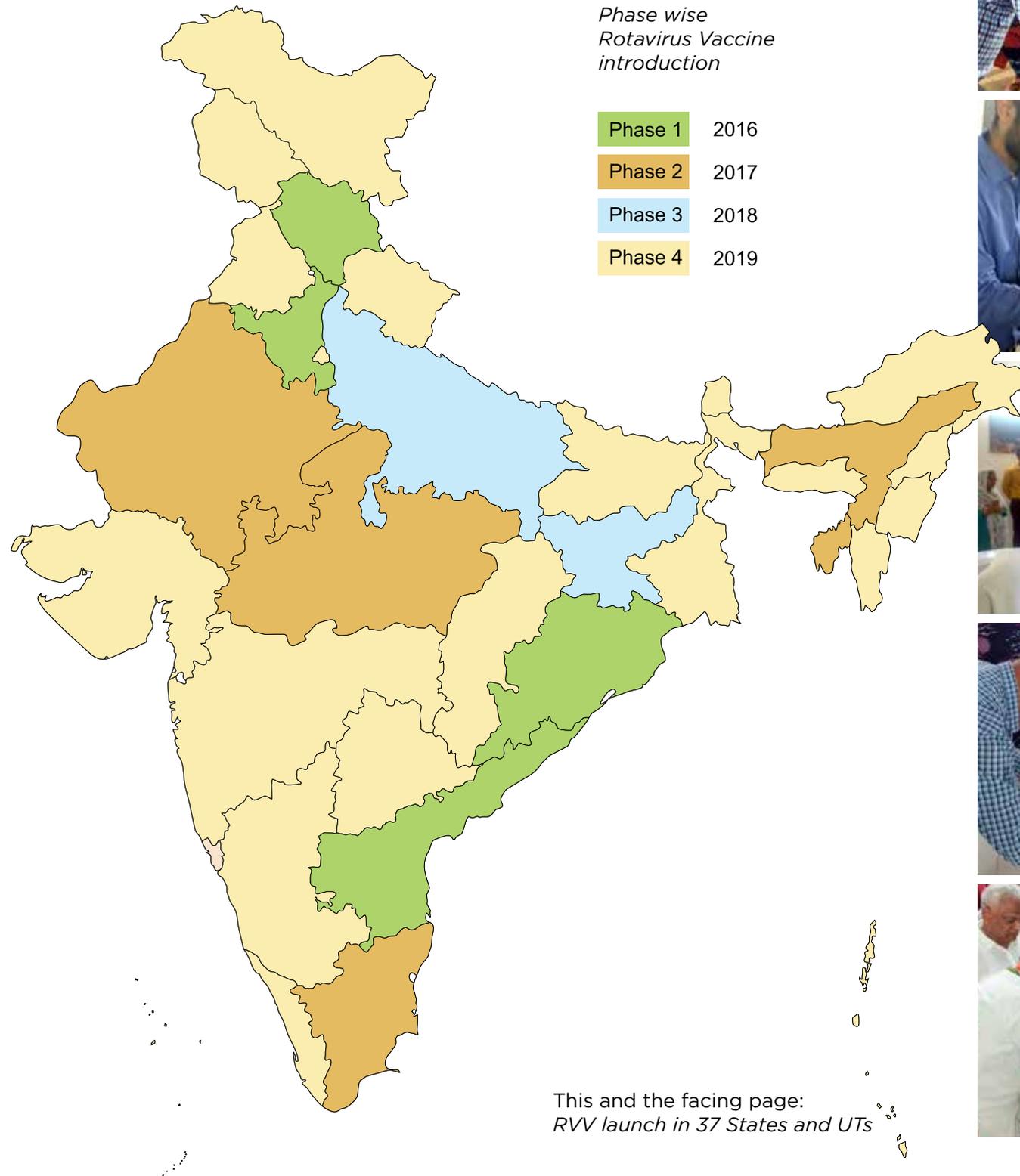


Inter Personal Communication (IPC) slips for beneficiary mobilization in Assam

With introduction of Rotavirus vaccine in the state, Government of Assam has developed invitation slips to mobilize the beneficiaries for vaccination at immunization sessions. The invitation slips have been developed in three languages – Assamese, Bengali and English to cover the diverse population of the state. The slip helps ASHAs to communicate effectively with caregivers on the new vaccines and also eases communication on details of child’s due vaccine.

LAUNCH

Beginning March 2016, the Rotavirus vaccine was launched in a phased manner. In all thirty-seven provincial geographies Rotavirus vaccine was ceremonially launched by the highest level of political and administrative functionaries from the respective governments, from Andhra Pradesh to Arunachal Pradesh, from Kerala to Kashmir, from Ladakh to Lakshadweep, from Maharashtra to Manipur and from Punjab to Puducherry. The launch was covered by the national and local electronic and print media with great enthusiasm in more than 25 languages.



This and the facing page:
RVV launch in 37 States and UTs





FIRST CHILD VACCINATED



As Shri JP Nadda, Hon'ble Health Minister, Government of India instils these five historic drops of Rotavac, Somya Priyadarshani becomes the first baby to be vaccinated with Rotavirus vaccine in India's Universal Immunization Programme on March 26, 2016 at Bhubaneswar, Odisha. Dr. Rakesh Kumar, Jt. Secretary and Dr. Bhrigu Kapuria (JSI) were also present.

“Adding this life-saving vaccine to our immunization programme will not only improve the health of our children but also reduce hospitalization and other conditions associated with diarrhoea due to Rotavirus such as malnutrition, delayed physical and mental development among children. Reduced hospitalization reduces the economic burden on the family and the health cost burden on the country”.

JP Nadda, March 26, 2016



First baby being vaccinated through public health programme as part of Rotavac safety surveillance study on December 3, 2015 at Kangra, Himachal Pradesh



First baby (ID 10001) being vaccinated with Rotavac on March 11, 2011 in Phase III clinical trial at Delhi



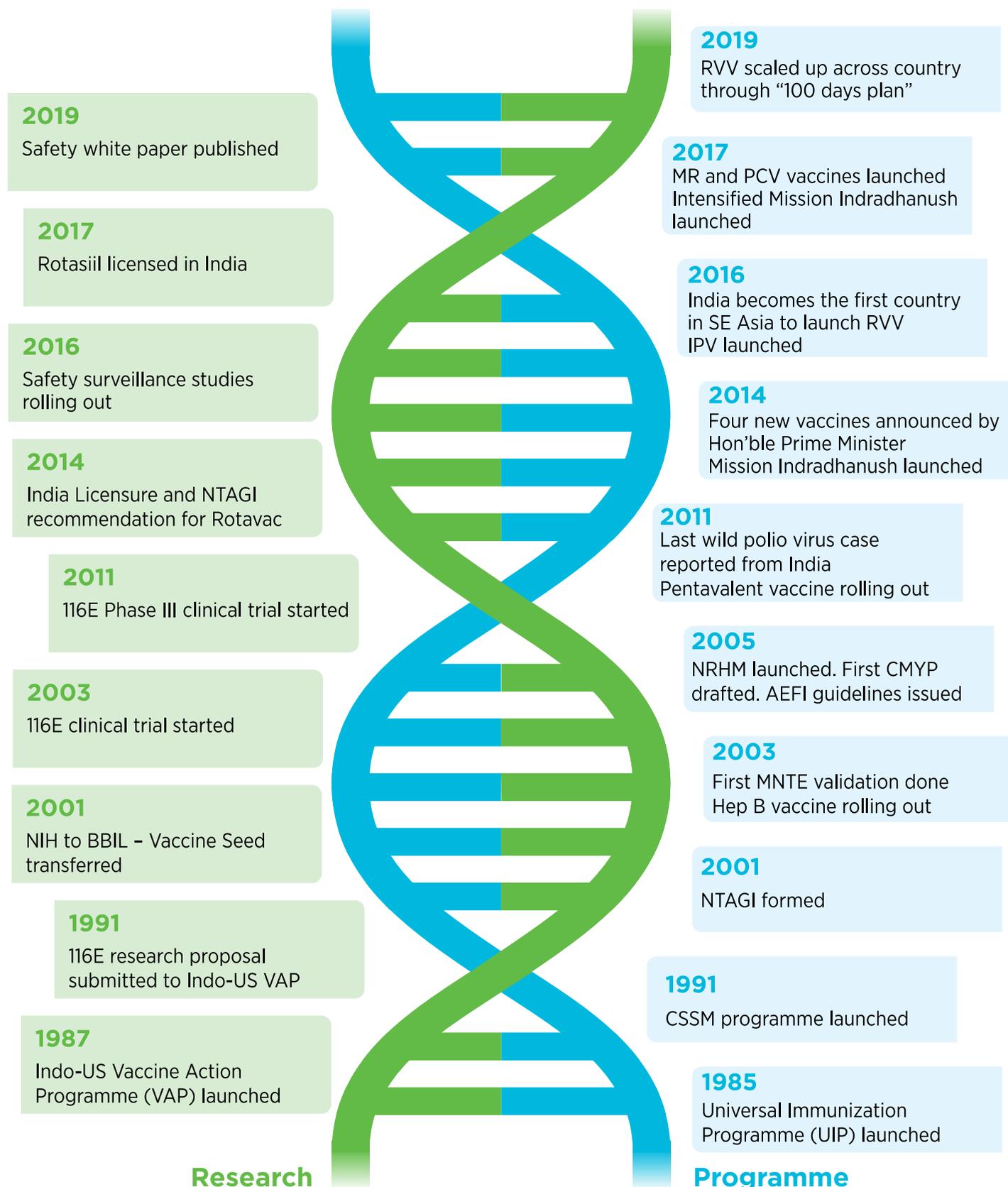
Rotavirus vaccine administration - Rotasiil



Rotavirus vaccine administration - Rotavac

The Routine Immunization Programme matured over the years with the introduction of newer vaccines, intensification through special drives and other achievements. At the same time, the work on the development of indigenous Rotavirus vaccine was going on which culminated in the introduction of vaccine in the UIP.

Major milestones in RVV Research and Routine Immunization Programme





Rota in numbers

INTENSIFICATION

Introduction and adoption of new vaccines is critical to improving child health and survival in the developing world. Often, such introductions present certain challenges, including lack of awareness of the value of the vaccine, issues related to inadequate health systems, and insufficient planning and financing. India conquered every challenge to not only introduce the vaccine in a safe and seamless way, but also progressed on steady expansion to eleven large states in three years (2016–2018). In 2019 itself, the government has achieved an unprecedented speed in scaling up Rotavirus vaccine to 25 remaining states and union territories in just one hundred days, ensuring access of Rotavirus vaccine to total 26.7 million infants.

Phase	Reach
Phase 1 (2016)	2.4 million
Phase 2 (2017)	5.6 million
Phase 3 (2018)	6.6 million
Phase 4 (2019)	12.1 million

With rapid scale up of the Rotavirus vaccine, the government also undertakes periodic intensification of routine immunization (PIRI) in the name of Intensified Mission Indradhanush (IMI). This has resulted in 18.5 percent point increase in full immunization coverage in the selected IMI districts. IMI campaign has been selected as one of the twelve best practices from around the world, to be featured in a special issue of the British Medical Journal. For accelerating annual coverage improvement rate from 1 to 6.7 percent, the programme has received high praise in a global report card by Johns Hopkins Bloomberg School of Public Health.

Extra efforts taken to reach remote areas in difficult terrains under IMI

“The Health Ministry has drawn plan under the 100-day agenda of the newly-elected government, wherein it has been decided to provide Rotavirus vaccine to every child across all 36 States and Union Territories (UTs) by September 2019.”

**Dr. Harsh Vardhan,
Hon’ble Minister of Health
& Family Welfare,
Government of India
August 9, 2019**

OUTREACH

In India, on an average, 12 million immunization sessions are organized every year across tertiary hospitals, community and primary health centers, sub centers, Anganwadi centers and outreach sites. The outreach sessions constitute a major share (59 percent of the vaccination given through the public health system), which has enabled the system to reach the last mile across this vast country of diverse and difficult terrains, through hilly cliffs and riverine islands, through flood plains and dense forests, through urban slums and arid deserts. The alternate vaccine delivery system remains key to ensure vaccine supply to every session site. The immunization sessions are usually linked to the Village Health Sanitation and Nutrition Days (VHSNDs), being organized once every month at the Anganwadi Centre in the village. On the VHSN day, ASHAs, AWWs, and others mobilize women and children to the outreach session sites.

“I came to know from ASHA didi that now a vaccine is available free of cost at Government centres which will protect our children from diarrhoea. Today, I have started with the course of this vaccine for my child. I plea that all parents should get their child vaccinated to keep them safe and healthy.”



**Preeti Patel, mother of a two months old baby
Damoh, Madhya Pradesh**





Frontline workers are on the way to conduct an IMI session at Sonwada, Alirajpur district, Madhya Pradesh

Session going on in a brick-kiln at Nagarnausa, Nalanda, Bihar



OUTREACH: FIELD STORY

Rotavirus Vaccine: Vaccinators' priority

Session Site: Nawadiya village, Block: Milak, District: Rampur, Uttar Pradesh. January 19, 2019

An outreach session at village Nawadiya was held on January 19, 2019. There were 13 beneficiaries for RVV in the due list. The ANM, named Nafis Bano, found that only two vials of RVV (five dose vial of liquid RVV) were supplied from the Cold Chain Point (CCP). With these two vials she was able to vaccinate only 10 children and for the rest she needed one more vial.

Immediately, she requested the alternate vaccine delivery (AVD) person to go and bring one more vial of RVV from the CCP. The AVD person went to the CCP immediately and brought back one vial of RVV. The ASHA went out to the village and mobilized the remaining three beneficiaries to the session site. All of them received RVV and none were left out. This proved the ANM's proactiveness and initiative to immunize all children on the vaccination day. She said "the children should not miss the due dose due to our mistakes". It is a lesson for everyone in the field who is providing health care services to community that little effort and proactiveness goes a long way in getting desired result and achievement.

Rotavirus vaccine helping to turn the tide

Session Site: Anganwadi Centre Dwarka Puri, Sarvodaya Nagar, Kanpur, Uttar Pradesh. October 23, 2018

Reshma, a 28 years old homemaker lives with her two daughters, husband and in-laws in Kanpur city of Uttar Pradesh (UP). Traditionally, the residents of her locality avail health care services from private facilities. When she was pregnant with her second child, the ASHA and Anganwadi worker tried to convince her to avail antenatal services from government facilities, but her family continued with their preference for the private facility. Her second child was born at home and no vaccines were administered to her.

In the meanwhile, one of her relatives had to incur a huge expenditure when their child had to be admitted in a private hospital with severe diarrhoea. Coincidentally, during that time, Rotavirus vaccine was being introduced in UP and the ASHA worker had come to her home to explain about the new Rotavirus vaccine (RVV), which would protect the child from 'gambhir dast' (severe diarrhoea). She wanted to protect her child from severe diarrhoea but found out that she would have to spend a lot of money to get the vaccine at the private facility. She finally convinced her family to take the child to the nearest government immunization session site. On October 23, 2018, she came to the session site and her child got the first dose of RVV free of cost. The child was also administered the first dose of IPV, OPV and Hib containing Pentavalent vaccine. Now, she is convinced that vaccines which are available in the government programmes are of high quality, free of cost and must be taken by the community to protect their children.



Reshma got her daughter vaccinated for RVV by Santosh (ANM) in presence of Poonam (ASHA) and Meena (AWW)



An ANM is crossing the baid-bar to reach the session site in Dhubri District of Assam



“We travel along road to success throughout our lives by overcoming barriers. Similarly Rotavirus vaccine introduction also became a success story by overcoming various barriers. RVV introduction is the perfect example of coordination among the stakeholders wherein government, partners and professional bodies worked hand-in-hand to prevent children from diarrhoeal fatalities.”

Dr Santosh Shukla, State EPI Officer, Madhya Pradesh, India



ANM and ASHA are climbing up to conduct an IMI session at Malana (8,701 feet) in Kullu district of Himachal Pradesh. It takes 40 minutes ride and more than four hours' trek for them to reach the site from their centre.





Promotional banner for Intensified Mission Indradhanush

INTENSIFICATION: FIELD STORY

It is a quiet April afternoon in the interiors of Bahsuma, a *nagar panchayat* (city council) of Meerut. There is seldom any human activity in the alleys here. In one such alley, interrupting the quietness, often there are a couple of voices reminding the neighbourhood that *it is Wednesday*. Annu and Harinder are walking steadily with their characteristic gait of post-poliomyelitis. Harinder (28), is a tailor like many others in his village. But today, he tells his clients, visiting him, to wait till he comes back. Annu (23), has also finished her household work early. Both of them are in a hurry to take their two children for immunization. On their way, they are also calling other parents to take their children for immunization. Routine Immunization (RI) session is going on in Bahsuma like every other Wednesday.

Harrinder and Annu married five years back. Their parents were looking for a bride and a groom for their respective child. In villages like Bahsuma, the villagers still believe that if someone marries a polio-affected person, their next generation will be '*apahij*'.

"We both faced social and economical obstacles because of our disabilities. Our society, even our own family and relatives, never accepted us as normal beings. But it was no fault of ours. If we have to blame someone, then they are our parents and their lack of awareness about immunization. We do not want to repeat the same mistake with our children. It's not just polio, but we want to protect our children from all preventable diseases", Annu summarised the reason behind their eagerness to attend the RI session.

Both their children, aged four and two, never missed a single immunization. Villagers also are now coming forward to get their children immunized.





एक बिल्ली के लिए
एक फूल
एक पत्ता
एक फल

MONITORING & REVIEW

After the launch of the vaccine, intensive field monitoring was undertaken by the supervising health officials and representatives from partner agencies, using a standard checklist and a GPS-enabled mobile application for the Cold Chain Points and the immunization session sites. This intensive monitoring helps the programme personnel to identify the critical implementation gaps and guide the field level functionaries to undertake mid-course correction by providing real-time actionable data. Key indicators from the monitoring checklists were incorporated in the routine immunization monitoring process. During Intensified Mission Indradhanush, the monitoring was being personally conducted by the highest level of officials from the Government of India and the State Governments.

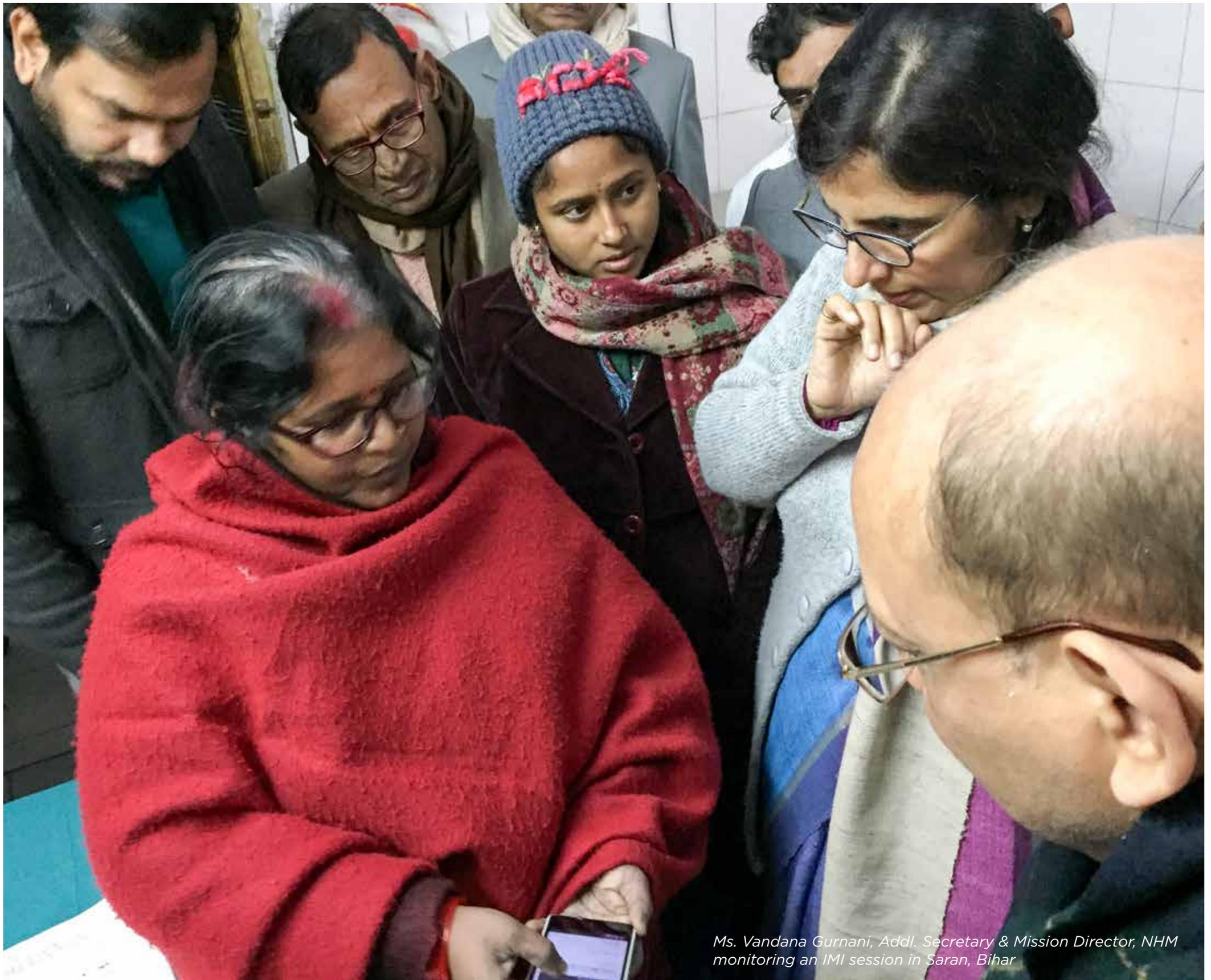
State and district task forces at their respective levels continue to act with the mandate to convene periodically to discuss the progress, and prepare action points on the way forward to address any challenges emerging during the implementation of activities necessary for effective vaccine introduction. WHO (NPSP), UNICEF, JSI and other key routine immunization partners involved in immunization at state and district levels actively participated in the meeting and provided programmatic support.



Dr. SK Sikdar, Addl. Commissioner (Immunization), monitoring an IMI session in West Bengal

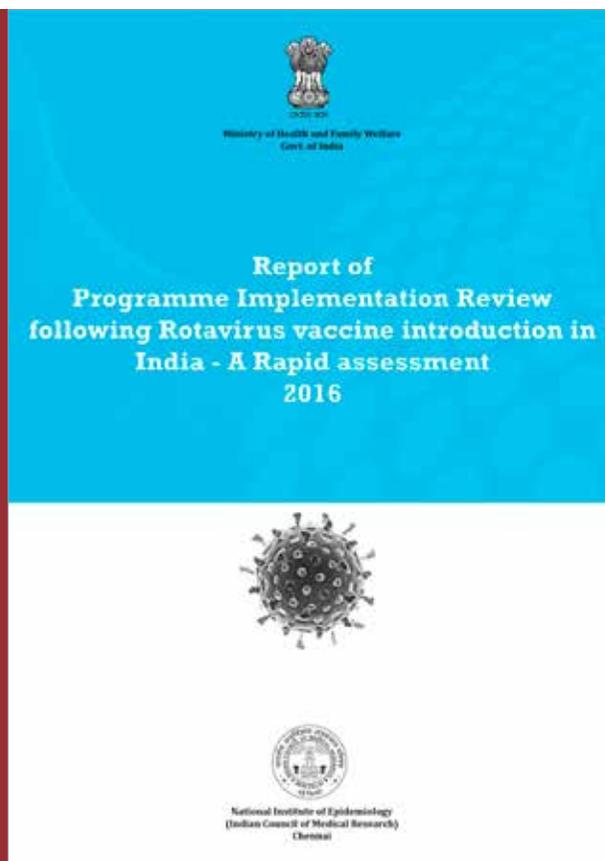


Dr. MK Agarwal, Joint Commissioner (UIP) monitoring an IMI session at Patna



Ms. Vandana Gurnani, Addl. Secretary & Mission Director, NHM monitoring an IMI session in Saran, Bihar

As recommended by the NTAGI, Indian Council of Medical Research conducted a mid-term Programme Implementation Review (PIR) to understand the processes, identify challenges and suggest mitigations from the first phase of Rotavirus vaccine introduction in four states in September 2016. The PIR found the Rotavirus vaccine implementation quite satisfactory in terms of all programme components and recommended a country-wide scale-up. The Government of India also reviewed the performance of the states introducing RVV in a review workshop in August 2017.



Overall, the first phase of Rotavirus vaccine introduction, done in the four states with diverse topological, epidemiological, demographic and programmatic settings, has been smooth and successful. Furthermore, programmatically the introduction has focused on overall system strengthening approach. Rotavirus vaccine was well accepted by Health workers, community, mothers, caregivers and media.



Ministry of Health & Family Welfare
Government of India



NATIONAL ROTAVIRUS VACCINE INTRODUCTION REVIEW WORKSHOP

August 2017

Connaught Hotel, New Delhi

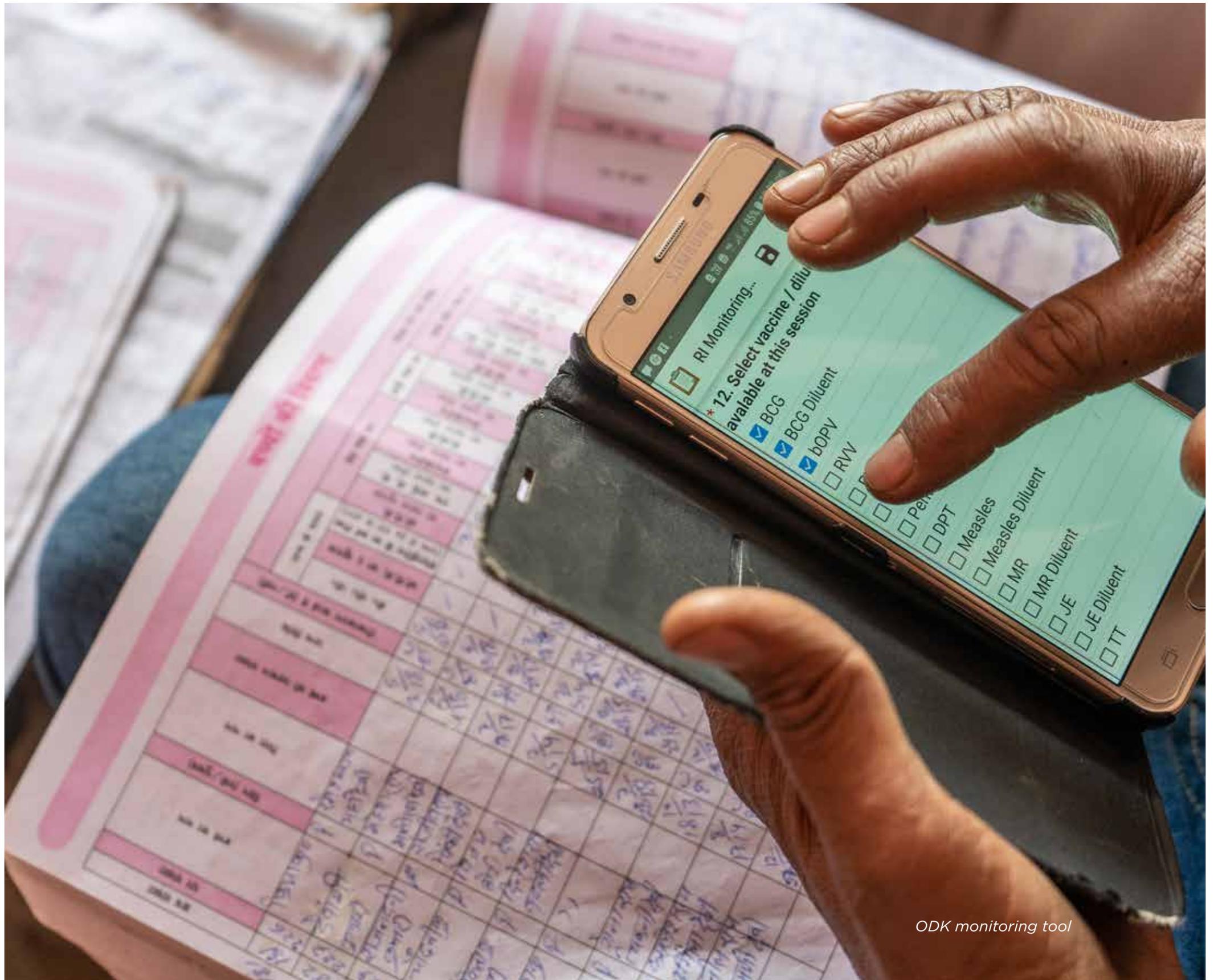
Be Wise!
Get your child
immunized



Dr. Veena Dhawan

Dr. M K Agarwal

Dr. Neeta Bhandari



ODK monitoring tool



Dr. Ajay Khera, Commissioner - Public Health, monitoring house-to-house in Gujarat

INTERCHANGEABILITY

India, for the first time, introduced two Rotavirus vaccine products, manufactured by two Indian companies, under the Universal Immunization Programme. Out of thirty-seven states and union territories, twenty-six are using Rotavac and eleven are using Rotasiil. This mixed product use leads to the possibility that children migrating from one state to another may need to be vaccinated with different products to complete their Rotavirus vaccination series at 6, 10 and 14 weeks of age. This programme necessity drives the government to review global evidence on interchangeability of Rotavirus vaccines, and based on the available evidence, interchangeable use of Rotavac and Rotasiil has been allowed in the programme.

This programmatic step taken by India has three major beneficial implications:

- It helps in timely completion of age appropriate immunization for migratory children
- It also helps parents to switch from private providers to public programme, improving equity and reducing out of pocket expenses for the families
- It becomes a template for other countries to follow in future Rotavirus vaccine introductions/product switches.

In parallel to this programme directive, the Immunization Division has also commissioned the world's first head-to-head Rotavac-Rotasiil interchangeability study by Indian Council of Medical Research (ICMR) at the National Institute of Cholera and Enteric Diseases (NICED), Kolkata.



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.

सभी सिविल सर्जन
को सूचना के तहत सापेक्ष
कार्य हेतु प्रेषित
जापांक-1300 (रिजिस्ट्रार) 16/04/19
(अपर निदेशक)

Yours faithfully,

Dr Pradeep Halder
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, GHIS



Interchangeability study site at
Dr. BC Roy Post Graduate Institute of
Paediatric Sciences, Kolkata

INNOVATIONS

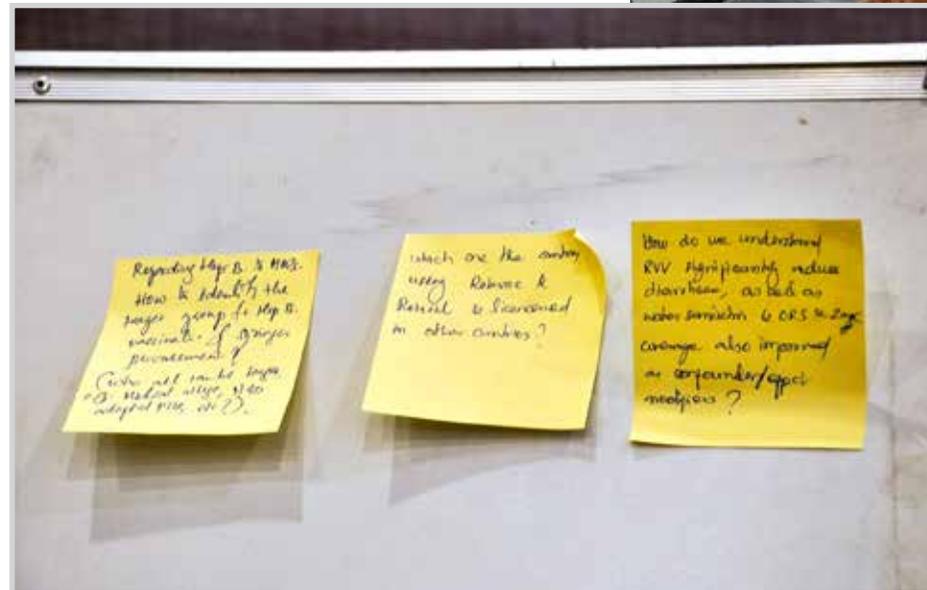
The Rotavirus vaccine introduction in India provided the ideal opportunity to try out user friendly and scalable innovations to add value to the quality of routine immunization programme implementation. These innovations were embedded in the UIP to support immunization efforts.

On request from Immunization Division, Government of India, the manufacturer conducted trials of Rotavac vaccine without buffer and established its efficacy. They also carried out nine freeze-thaw cycles to demonstrate its stability for use in the field. This optimized storage and administration of the vaccine in the programme. Rotavac is the world's first RVV without buffer.

A “station approach” was devised to allow for hands-on training to small groups in an interactive way for better and quicker understanding and skill development. Online pre- and post- test were conducted during the training sessions. This was followed by telephonic assessments of knowledge retention by the trainees, and wherever required, the trainees were reoriented. Specifically for Rotasiil, customized job aids were developed for cold chain handlers and vaccinators. A GPS-enabled tool was deployed to monitor Cold Chain Points and session sites. A bi-monthly newsletter called “*RotaTalk*” was developed for cross fertilization of ideas and initiatives across the states.

These best practices have been shared at global forums through oral and poster presentations at 12th and 13th International Rota Symposiums, Asian EPI Managers Meeting and Rotavirus Accelerated Vaccine Introduction Network (RAVIN) meetings.

Sticky notes capturing audience questions



Station approach in RVV training





Cold Chain & Vaccine Logistic Management

Ministry of Health & Family Welfare
Government of India

NATIONAL VACCINE INSTITUTE
National Institute of Immunology





Cold Chain & Vaccine Logistic Management

Ministry of Health & Family Welfare
Government of India

NATIONAL VACCINE INSTITUTE
National Institute of Immunology

WTC

- GMSD
- State
- Regional
- District
- Cold chain point
- Session site

Till cold chain point

RVV should be transported in cold boxes with conditioned ice-packs along with other UIP vaccines

Session site

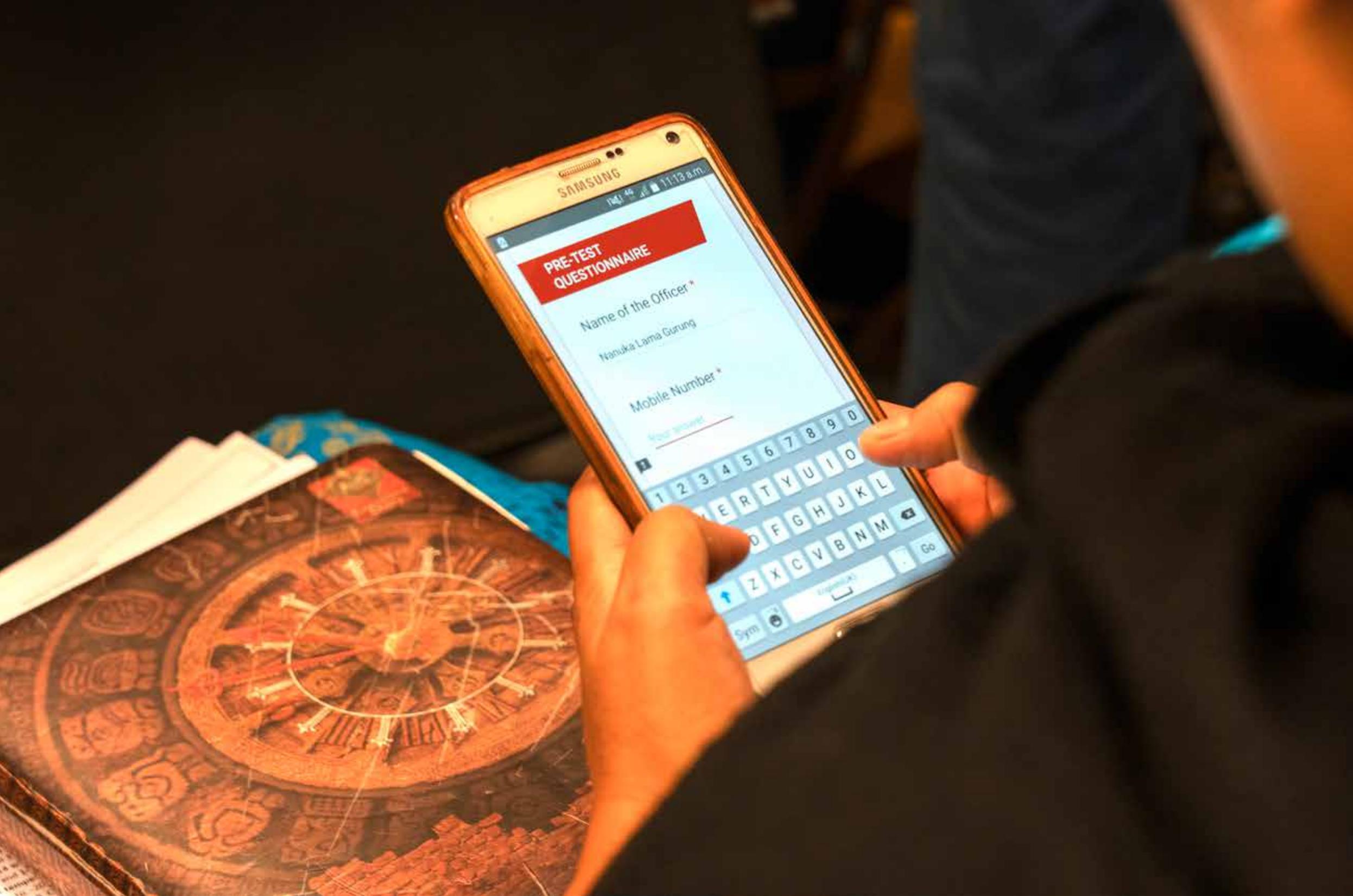
RVV should be transported to session sites along with other vaccine in vaccine carrier with conditioned ice packs.

PERMISSIBLE WASTAGE RATES

10% and the storage multiplication factor is 1.11.

RECORDING OF RVV STOCK & ISSUE





Online pre- and post test questionnaire during RVV training

INNOVATIONS: FIELD STORY

Innovative mobile application for Supportive Supervision of Rotavirus Vaccine introduction in Uttar Pradesh

For providing mentoring support and overall system strengthening, JSI has developed a supportive supervision tool for Rotavirus Vaccine introduction. It is for the Vaccine and Cold Chain Handlers as well as Health workers at the cold chain points and session sites respectively. For this purpose a mobile application has been designed with the following features:

- Captures real-time data
- GPS enabled data collection process helps in geographical mapping of the sites and the validation features helps to improve the accuracy and quality of data
- Weighted scores for the questions to obtain component-wise score as well as cumulative scores for each of the sites visited. This also helps in ranking the facilities and measuring the value addition by supportive supervision visits
- Dashboard and analyzed indicators help in advocacy with programme officers at district and state level for faster decision making process.



Mobile phone App developed for Supportive supervision of RVVI

Using technology for direct reporting

Frontline health workers are the heart of the public health system in India. They bear the burden of improving the health status of the country.

Suman Kumari working as ANM in Health Sub Centre Alipura in district Dausa, Rajasthan is collecting data using information technology (IT) and entering data directly in Parent and Child Tracking System (PCTS) which is shared with block, district and state officials for optimal use of data for policy making.



"I am following the practice of using the laptop for direct reporting since last three years. This practice not only saves me a lot of time which was earlier consumed in doing the paperwork but it also helps in easing the burden and organizing my work better."



Dr. Pradeep Haldar and Dr. Duncan Steele with the bi-monthly newsletter RotaTalk

Best practices dissemination meeting ►



VACCINE
PRODUCT
RELATED



JSI

- Complicated bundling approach. With every vaccine vial, 1 diluent vial, 1 adapter and 2 and syringe have to be bundled together.
- Special one day training workshop for GCMs, side on bundling approach developed.
- Facility requisition and administration difficult.
- Comprehensive hands on training, training



INTEGRATION

While sanitation and safe and clean water supply can prevent water borne bacterial infections, Rotavirus vaccine is needed to specifically prevent severe Rotavirus diarrhoea. We also know that enteric and diarrhoeal diseases lead to chronic malnutrition, which demand adequate nutritional supplementation.

To ensure holistic development of children, the Government of India launched the Integrated Action Plan for Prevention and Control of Pneumonia and Diarrhoea (IAPPD) in 2014, based on the WHO's Global Action Plan for Prevention and Control of Pneumonia and Diarrhoea (GAPPD), which incorporates seven interventions: fluid replacement to prevent dehydration, zinc treatment, Rotavirus and measles vaccination, promotion and early and exclusive breastfeeding and Vitamin A supplementation, promotion of hand washing with soap, improved water supply quantity and quality, including treatment and safe storage of household water and community wide sanitation promotion.

Hand washing being promoted in a diarrhoea ward

हाथ धोने के तरीके





“Public health strategies are never one-dimensional, and it would be imprudent to undermine tried and tested interventions. Sanitation, clean drinking water, breastfeeding and hygiene are essential, even crucial, but so is immunizing children with safe vaccines.”

Dr. Vinod Paul, Lead - Health & Nutrition, NITI Aayog



Immunization awareness messages along with gender and health literacy initiatives, Bihar



Hand washing being promoted at an immunization session site, Barwani, Madhya Pradesh



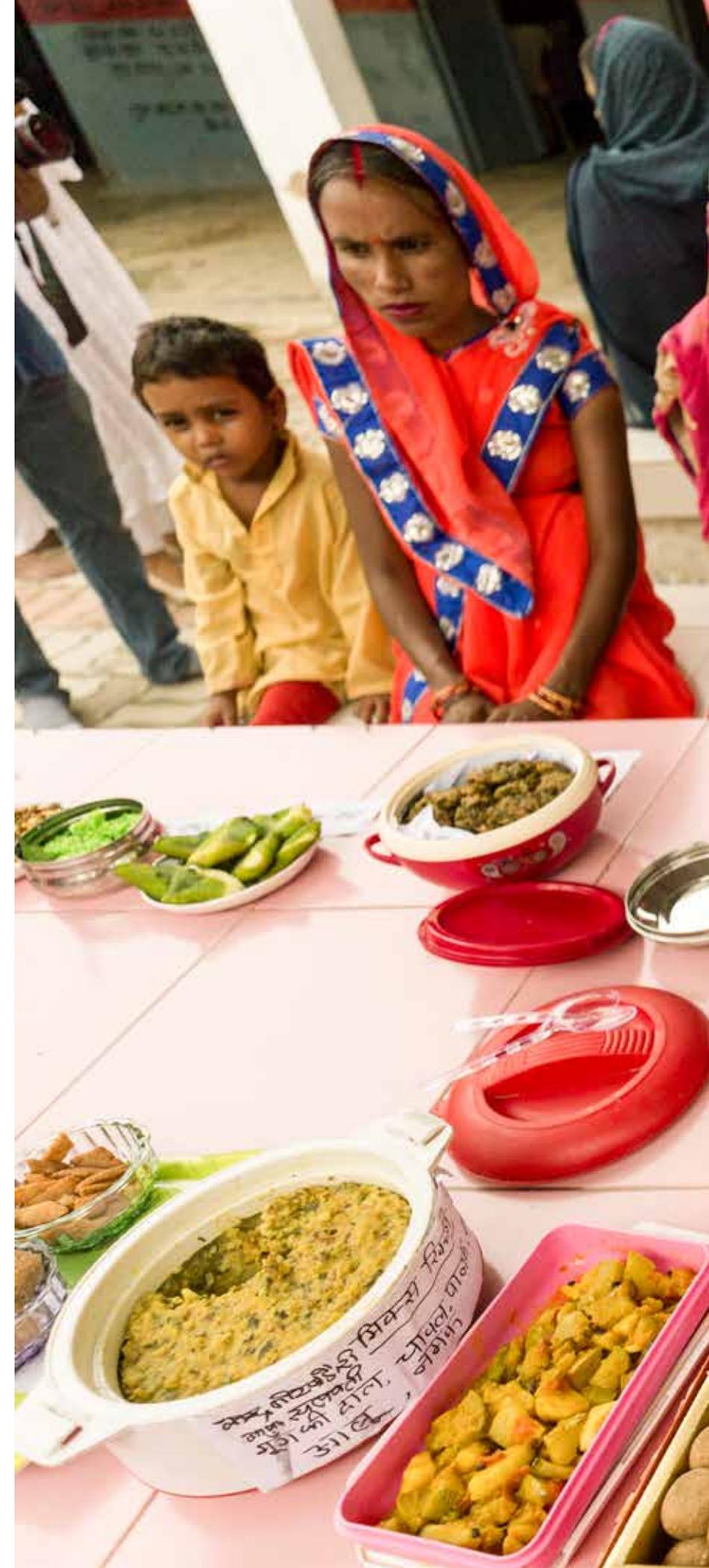
To accelerate the efforts to achieve universal sanitation coverage and to put focus on sanitation, the Prime Minister of India launched the Swachh Bharat Mission on October 2, 2014 which has led India to become free of open defecation and avert 300,000 deaths from diarrhoea and malnutrition between 2014 and 2019. This success has been globally recognized with the Prime Minister receiving the “Goal Keepers Award” for 2019.

The Prime Minister’s Overarching Scheme for Holistic Nutrition (POSHAN) Abhiyaan or National Nutrition Mission (NNM), is Government of India’s flagship programme to improve nutritional outcomes for children, pregnant women and lactating mothers. Launched by the Prime Minister on the occasion of the International Women’s Day on March 8, 2018, the POSHAN Abhiyaan directs the attention of the country towards the problem of malnutrition and address it in a mission-mode. An integral strategy of this mission is to expand the coverage of Rotavirus vaccine to the entire country to protect the children from Rotavirus diarrhoea.



Toilet made with indigenous materials like mud-packed bamboo and clay, painted with rich colours in Kanhai village which is now open defecation free. Its 101 houses have 101 toilets and 101 unique facades.

Recipe contest among rural women as a part of ‘POSHAN Abhiyaan’ in Bihar





चन्ना मुगफली
क्री पट्टी देवा
आ० वा० आशा देवा
कै-३- इलासपुर

आ० वा० मणिक
वालिगा
कै-३- टंडा

कौजदार
क्री
कौजदार
कै-३- टंडा

INTEGRATION: FIELD STORY

Training resource material developed for Integrated Management of diarrhoea in Tamil Nadu

A comprehensive training module in vernacular language (Tamil) was prepared for health workers and medical officers to build their capacity for diarrhoea prevention and control by Tamil Nadu government. In addition to Rotavirus vaccine, this module also details about the multi-pronged strategy of prevention and control of diarrhoea such as Intensified Diarrhoea Control Fortnight (IDCF) – promotion of use of ORS and Zinc, Mothers Absolute Affection (MAA) – for promotion of exclusive breastfeeding, Swachh Bharat Abhiyan, use of safe water and Vitamin A supplementation. This innovation is a significant step in advocating and generating demand for Rotavirus vaccination among the community and at the same time focusing on existing measures already in place to improve the sanitation, hygiene and overall growth and development of the children.



“Rotavirus diarrhoea is difficult to diagnose & expensive laboratory investigations are required for prompt diagnosis. Most important and specific tool for prevention is Rotavirus vaccine. I congratulate the government for introducing Rotavirus vaccine free of cost for general public especially poor, underserved and marginalized population. It would definitely help to reduce severe Rotavirus diarrhoeal deaths & hospitalizations in the country. It is a great initiative by Government of India.”



Dr. Himanshu Kelkar, Senior Paediatrician at Medanta Hospital, Indore



Dr. C. Vijaya Baskar, Hon'ble Health Minister of Tamil Nadu along with Dr J Radhakrishnan IAS, Principal Secretary Health and Dr. K. Kolandaswami, Director Public Health inaugurating the integrated training material developed by state government in collaboration with JSI for Rotavirus vaccine introduction in the state



Dr. C. Vijaya Baskar, Hon'ble Health Minister of Tamil Nadu doing media advocacy for integrated diarrhoea control including Rotavirus vaccine, in presence of Dr. J Radhakrishnan IAS, Principal Secretary Health and Dr. K. Kolandaswami, Director Public Health



Dr. J Radhakrishnan IAS, Principal Secretary Health chairing the State task force for introduction of Rotavirus vaccine as a part of integrated diarrhoea control strategy. The meeting is being attended by representatives from Directorate of Public Health and Preventive Medicine, Directorate of Medical Education and all partner organizations including IMA and IAP

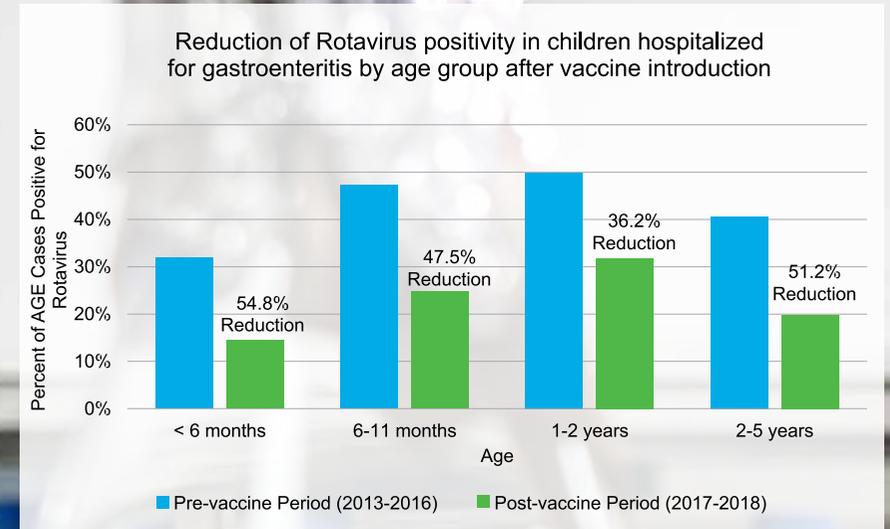
IMPACT

National Rotavirus Surveillance Network (NRSN) expanded from eight hospitals in 2012 to 34 hospitals in 2019. This expansion allows generation of more geographically representative Rotavirus hospitalization data across the country, which continues to inform the decision making process of the government. The same surveillance network is also utilized to generate Rotavirus vaccine safety data by capturing intussusception cases. Thus, both the disease and vaccine safety data, as collected by this network, helps the government to assess the impact in terms of reductions in child deaths and hospitalizations from Rotavirus Acute Gastroenteritis (AGE) as well as detect any safety signals. India, having the largest cohort of infants, provides an opportunity to detect rarer adverse events following Rotavirus vaccination. The Rotavirus AGE surveillance data from pre and post vaccine introduction time period clearly shows reduction in hospitalizations in all sites.



Specimens for culture

Dr. Gagandeep Kang,
Executive Director
- THSTI leads the
Rotavirus vaccine
impact study





ACRONYMS

AEFI	Adverse Event Following Immunization	GEMS	Global Enteric Multi Centre Study	NTAGI	National Technical Advisory Group on Immunization
AIIMS	All India Institute of Medical Sciences	GHS	Global Health Strategies	ORS	Oral Rehydration Solution
ANM	Auxiliary Nurse Mid wife	IAPPD	Integrated Action Plan for Prevention and Control of Pneumonia and Diarrhoea	PIR	Program Implementation Review
ASHA	Accredited Social Health Activist	ICMR	Indian Council of Medical Research	PIRI	Periodic Intensification of Routine Immunization
ASMD	Additional Secretary cum Mission Director	IMI	Intensified Mission Indradhanush	POSHAN	Prime Minister's Overarching Scheme for Holistic Nutrition
AVD	Alternate Vaccine Delivery	INCLEN	International Clinical Epidemiology Network	RCH	Reproductive and Child Health
AWW	Anganwadi Worker	ITSU	Immunization Technical Support Unit	RVV	Rotavirus vaccine
BBIL	Bharat Biotech International Ltd	JSI	John Snow Inc	SAS	Society for Applied Studies
BMGF	Bill & Melinda Gates Foundation	KEM	King Edward Medical College	SEAR	WHO South East Asia Region
CDC	Centre for Disease Control	MI	Mission Indradhanush	SII	Serum Institute of India
CDSCO	Central Drug Standard Control Organization	MoH	Ministry of Health	THSTI	Translational Health Sciences and Technology Institute
CHAI	Clinton Health Access Initiative	MSG	Mission Steering Group	UIP	Universal Immunization Programme
CHRD	Centre for Health Research and Development	NCCVMRC	National Cold Chain and Vaccine Management Resource Centre	UNDP	United Nations Development Programme
CMC	Christian Medical College	NHM	National Health Mission	UNICEF	United Nations Children Fund
DBT	Department of Biotechnology	NICED	National Institute of Cholera and Enteric Diseases	USAID	United States Agency for International Development
DF	Deep Freezer	NIH	National Institute of Health	VAP	Vaccine Action Programme
EPC	Empowered Programme Committee	NIHFW	National Institute of Health and Family Welfare	VHSND	Village Health Sanitation and Nutrition Day
EPI	Expanded Programme on Immunization	NPSP	National Public Health Surveillance Project	VVM	Vaccine Vial Monitor
eVIN	Electronic Vaccine Intelligence Network	NRSN	National Rotavirus Surveillance Network	WHO	World Health Organization
GAPPD	Global Action Plan for Prevention and Control of Pneumonia and Diarrhoea				

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