Ministry of Health
& Family Welfare
Government of India

सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

OPERATIONAL GUIDELINES

Introduction of Rotavirus Vaccine in the Universal Immunization Programme

Immunization Division

FEBRUARY 2018

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सत्यमेव जयते

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Foreword

It gives me immense pleasure to present the operational guidelines for introduction of the new type of Rotavirus vaccine in the Universal Immunization Programme (UIP).In the last few years, the scope of the UIP has expanded with the introduction of several new vaccines for protection against vaccine preventable diseases.

Diarrheal diseases are the leading cause of childhood mortality globally as well as in India. Diarrhea is responsible for about 9% of under-five deaths globally and 10% under five deaths in India. Available data indicates that Rotavirus is responsible for nearly 40% of moderate to severe diarrhea in under-five children amounting to 32, 70,000 outpatient visits, 8,72,000 hospitalizations and 78,000 deaths annually in India.

In March 2016, India became the first country in Asia to launch Rotavirus vaccine in the Universal Immunization Program (UIP). Introduction of Rotavirus vaccine is a milestone achievement in expanding the benefits of vaccines to all children. The Rotavirus vaccine is now being expanded to different states of the country in a phased manner.

These operational guidelines have been developed to support the introduction of a new type of Rotavirus vaccine which is a oral freeze-dried preparation. It is given in a dose of 2.5 ml with the help of an oral 6 ml syringe.

These operational guidelines are meant to enhance the capacity of the immunization programme managers, supervisors and health workers for operationalization of this Rotavirus vaccine.

I am hopeful that these guidelines will be immensely helpful to the state of Jharkhand to introduce this new type of Rotavirus vaccine. I appreciate the efforts of all experts who have supported the Ministry of Health Family Welfare to develop these guidelines.

(Vandana Gurnani)

PREFACE

LIST OF ABBREVIATIONS

AD	:	Auto Disable
AEFI	:	Adverse Events Following immunization
AVD	:	Alternate Vaccine Delivery System
ANM	:	Auxiliary Nurse Midwife
ASHA	:	Accredited Social Health Activist
AWW	:	Anganwadi Worker
BMGF	:	Bill and Melinda Gates Foundation
CARE	:	Co-operative for Assistance and Relief Everywhere
CBO	:	Community Based Organization
CHC	:	Community Health Centre
CMHO	:	Chief Medical and Health Officer
CMO	:	Chief Medical Officer
CRF	:	Case Reporting Form
DALY	:	Disability Adjusted Life Year
DF	:	Deep Freezer
DHS	:	District Health Society
DIO	:	District Immunization Officer
DM	:	District Magistrate
DTFI	:	District Task Force on Immunization
ELISA	:	Enzyme Linked Immunosorbent Assay
eVIN	:	Electronic Vaccine Intelligence Network
FAQs	:	Frequently Asked Questions
FCIF	:	Final Case Investigation Form
GoI	:	Government of India
GHS	:	Global Health Strategies
GMSD	:	Government Medical Stores Depot
GVAP	:	Global Vaccine Action Plan
HIV	:	Human Immunodeficiency Virus
HMIS	:	Health Management Information System
HRAs	:	High Risk Areas
HWs	:	Health Workers
IAP	:	Indian Academy of Pediatrics
IAPSM	:	Indian Association of Preventive and Social Medicine
ICDS	:	Integrated Child Development Services
ICMR	:	Indian Council of Medical Research
IEC	:	Information Education Communication
IPC	:	Interpersonal Communication
ILR	:	Ice Lined Refrigerator
IMA	:	Indian Medical Association
IMR	:	Infant Mortality Rate
INCLEN	:	International Clinical Epidemiological Network
INR	:	Indian Rupee

IRSSN	:	Indian Rotavirus Strain Surveillance Network
ITSU	:	Immunization Technical Support Unit
JSI	:	John Snow Inc.
LHV	:	Lady Health Visitor
MCP	:	Mother and Child Protection Card
MCTS	:	Mother and Child Tracking System
MDG	:	Millennium Development Goals
M&E	:	Monitoring and Evaluation
MLA	:	Member of Legislative Assembly
MO	:	Medical Officer
MP	:	Member of Parliament
MoHFW	:	Ministry of Health and Family Welfare
NCCVMRC	:	National Cold chain and Vaccine Management Resource Centre
NGO	:	Non Governmental Organization
NHM	:	National Health Mission
NIHFW	:	National Institute of Health and Family Welfare
NPSP	:	National Public Health Surveillance Project
NTAGI	:	National Technical Advisory Group on Immunization
ORS	:	Oral Rehydration Solution
PATH	:	Program for Appropriate Technology in Health
PCIF	:	Preliminary Case Investigation Form
PHC	:	Primary Health Centre
PIR	:	Programme Implementation Review
RMNCH+A	:	Reproductive Maternal Newborn Child and Adolescent Health
RNA	:	Ribonucleic Acid
RT-PCR	:	Reverse Transcription Polymerase Chain Reaction
RVGE	:	Rotavirus Gastroenteritis
SCID	:	Severe Combined Immunodeficiency Disease
SHS	:	State Health Society
SEPIO	:	State Expanded Programme on Immunization Officer
SIO	:	State Immunization Officer
SMNet	:	Social Mobilization Network
SMO	:	Surveillance Medical Officer
STFI	:	State Task Force on Immunization
ToT	:	Training of Trainers
UIP	:	Universal Immunization Programme
UNDP	:	United Nations Development Programme
UNICEF	:	United Nations Children's Fund
U5MR	:	Under five Mortality rate
URI	:	Upper Respiratory Infections
VVM	:	Vaccine Vial Monitor
WASH	:	Water Sanitation and Hygiene Interventions
WHO	:	World Health Organization
WIC	:	Walk-In Freezer

CONTENTS

CHAPTER 1

INTRODUCTION

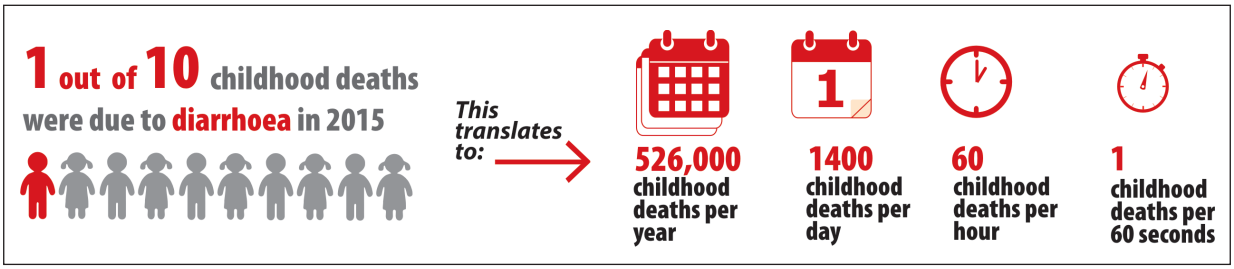
1.1 Purpose of these guidelines

These guidelines are meant to assist immunization programme managers at state, district and sub-district levels to introduce the oral freeze dried Rotavirus vaccine (RVV) in the Universal Immunization Programme (UIP). The intention is to provide information that is technically sound as well as operationally feasible.

1.2 Diarrhea in Children

Diarrheal diseases are the leading cause of childhood mortality globally as well as in India. Diarrhea is responsible for about 9% of under-five deaths globally[1] and 10% under five deaths in India translating to around 1.2 lakh deaths annually in India[2]. Available data indicates that Rotavirus is responsible for nearly 40% of moderate to severe diarrhea in under-five children amounting to 8,72,000 hospitalizations, 32, 70,000 outpatient visits and 78,000 deaths annually in India[3]. It has been observed that rotavirus infects Indian children at an age younger than the children in developed countries. Apart from burden of diarrhea and death due to rotavirus, diarrhea is also an important contributor to long-term nutritional deficiency complications like stunting, wasting, malnutrition and loss of cognitive development potential. Despite availability of several proven solutions for diarrhea, no single solution is sufficient for the prevention and treatment of rotavirus diarrhea. For India, it is estimated that the annual cost per disability-adjusted life year (DALY) averted due to rotavirus diarrhea is US$ 57 and 34% of rotavirus deaths can be averted through introduction of rotavirus vaccines.

Diarrhea kills too many children globally



Source: WHO and Maternal and Child Epidemiology Estimation Group (MCEE) estimates 2015[1]

In recognition of the global rotavirus disease burden, World Health Organization (WHO) has recommended inclusion of Rotavirus vaccines in the national immunization programme of all countries. Rotavirus vaccine is considered a priority particularly in countries with high rotavirus gastroenteritis (RVGE) associated fatality rates, such as South and South-Eastern Asia, and sub-Saharan Africa. The available Rotavirus vaccines have been introduced in 93 countries[4]. In countries where Rotavirus vaccine has been introduced, a significant reduction in hospitalization and death due to rotavirus has been documented.

The National Technical Advisory Group on Immunization (NTAGI), Ministry of Health and Family Welfare (MoHFW), Government of India (GoI) has recommended the introduction of Rotavirus vaccine in the country in a phased manner in the Universal Immunization Programme (UIP). So far, Rotavirus vaccine has been successfully introduced in nine States of the country namely Haryana, Himachal Pradesh, Andhra Pradesh, Odisha, Assam, Rajasthan, Madhya Pradesh, Tamil Nadu and Tripura. The RVV that is being used in these nine states is an oral, liquid vaccine. Each dose is of 5 drops and is administered with the help of a dropper supplied with the vaccine.

The MoHFW has received a new type of oral, freeze dried RVV. This is a lyophilized vaccine which has to be reconstituted before administration. Each dose is of 2.5 ml and is administered with the help of a 6-ml oral syringe supplied with the vaccine.

This operational guideline has been developed to facilitate smooth introduction of this new type of oral freeze-dried Rotavirus vaccine in UIP. Thus, these guidelines are applicable only for those states where this new type of RVV is introduced.

CHAPTER 2

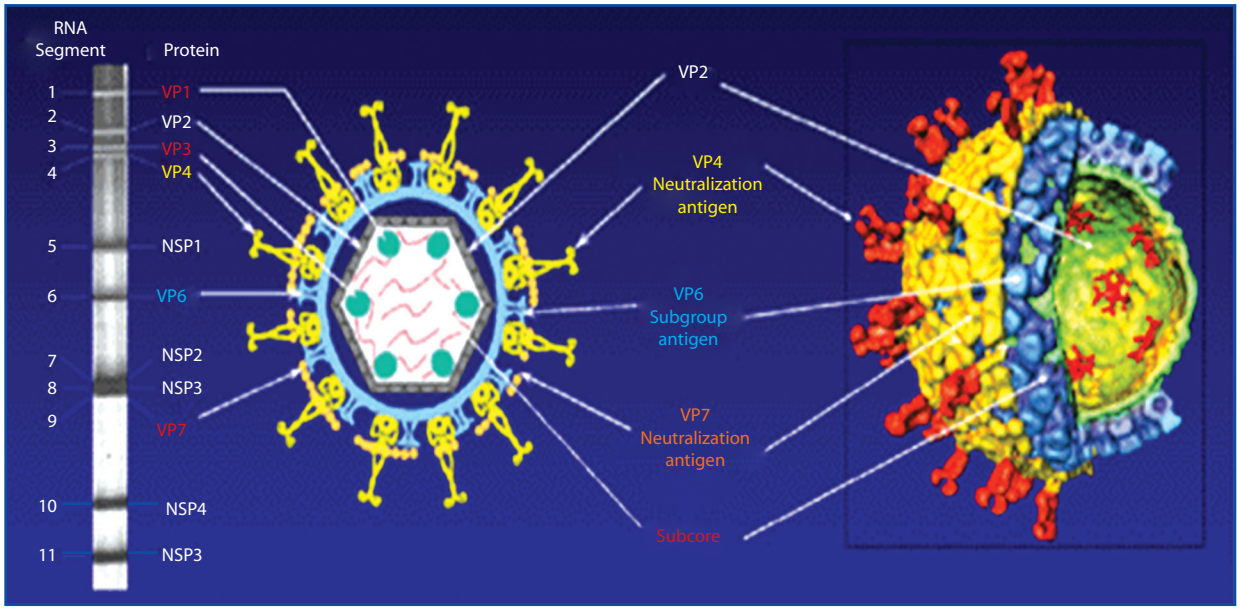
EPIDEMIOLOGY OF ROTAVIRUS DIARRHEA

2.1 Rotavirus

Rotavirus belongs to the viral family *Reoviridae,* which was named as "rota" virus due to its wheel-like shape as visible under an electron microscope. Apart from infection in humans, rotavirus infection has also been detected in many species of domestic animals, and wild mammals and birds, but animal-to-human transmission appears to be rare.

This triple-layered viral particle encompasses a viral genome consisting of 11 segments of double-stranded RNA that encode six structural viral proteins and six nonstructural viral proteins. The structural viral proteins in outermost viral layer; G protein and P protein are responsible for eliciting the production of neutralizing antibodies in the host and thus important for protective immunity. In humans, at least 19 G genotypes (14 serotypes) and 27 P genotypes (14 serotypes) have been identified. The combination of G- and P-types varies between strains and a binomial typing system is used to identify the strains. Rotavirus strains vary by region and by country. Currently, in large areas of the world, five G-P combinations (G1P[8], G2P[4], G3P[8], G4P[8] and G9P[8]) cause approximately 90% of all human rotavirus infections and among them, type G1P[8] is the most prevalent. In India, apart from the common serotypes G1P[8], G2P[4], G9P[8], and G9P[4], many other serotypes are also being detected. In addition, the prevailing types may differ considerably from one season to the next, even within the same geographical area.

Figure 1: Rotavirus structure and antigenic features



Source: CDC Rotavirus Factsheet 1998

2.2 Clinical Manifestations

The clinical spectrum of rotavirus illnesses is wide, ranging from transient loose stools to severe diarrhea with vomiting. This may result in dehydration, electrolyte imbalance, shock and death if not treated adequately. Following an incubation period of 1–3 days, the illness can begin abruptly, with vomiting often preceding the onset of diarrhea. Up to one-third of patients may have fever. Gastrointestinal symptoms generally resolve in 3–7 days. Children with rotavirus infection often suffer frequent vomiting that makes it difficult to administer oral rehydration solution (ORS) at home; and requires hospitalization. Although, in most cases recovery is complete, fatalities due to rotavirus diarrhea may occur mainly in infants.

The first infection is usually the most severe; later infections may be milder or asymptomatic due to previously acquired cross-immunity. Protective immunity against rotavirus infection is mediated by both humoral and cellular components of the immune system. Following first infection, the serological response is directed mainly against the specific viral serotype, whereas a broader, heterotypic antibody response is elicited following more than one subsequent rotavirus infections.

2.3 Global burden of Rotavirus diarrhea

According to the WHO (2013), rotavirus is responsible for more than 2,15,000 deaths each year in children younger than five years of age and 3.4% of all under-five deaths worldwide. Rotavirus is also responsible for millions of hospitalizations and clinic visits each year. It affects children around the world in both rich and poor countries. While rotavirus deaths and hospitalizations vary by region and country, the vast majority (95 percent) of rotavirus deaths in young children are found in low-and middle-income countries in Sub Saharan Africa (121,000). Four countries (India, Nigeria, Pakistan, and Democratic Republic of Congo) accounted for approximately half (49%) of all estimated rotavirus deaths in 2013 and 10 countries (India, Nigeria, Pakistan, Democratic Republic of Congo, Angola, Ethiopia, Afghanistan, Chad, Niger, and Kenya) accounted for almost two-thirds of all estimated rotavirus deaths. India bears the highest burden accounting for 22% of worldwide rotavirus deaths[5].

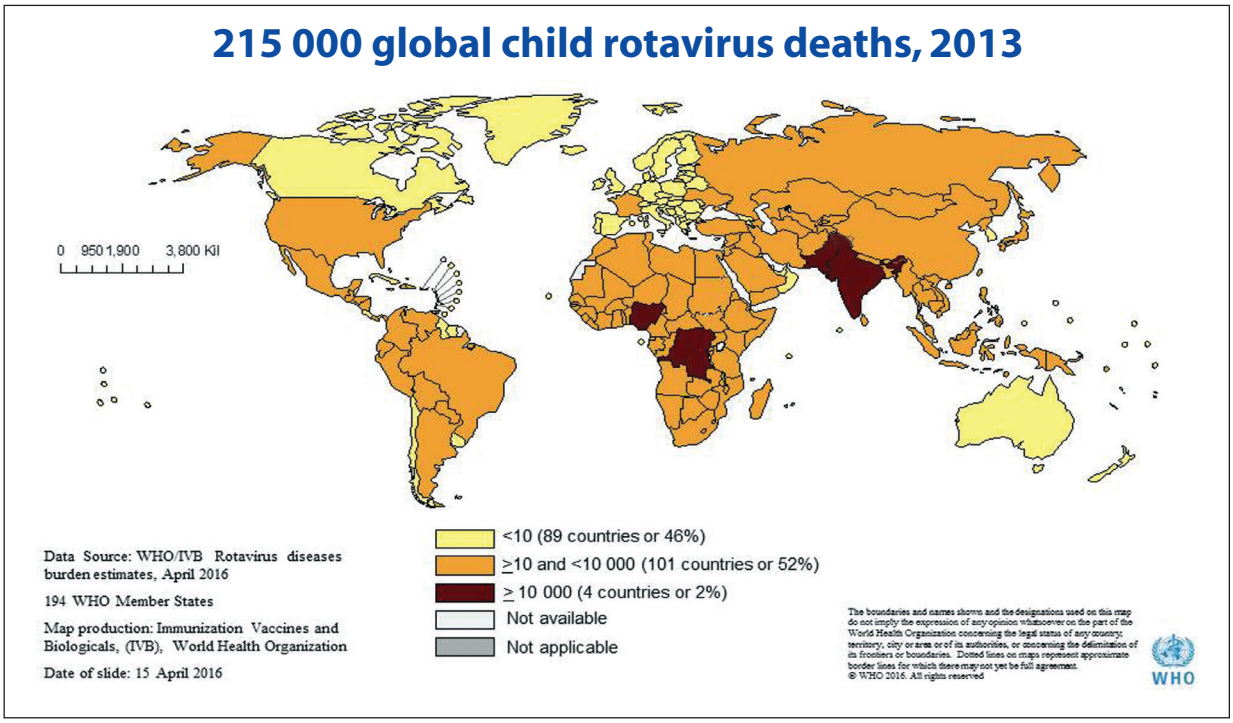
Rotavirus is estimated to cause 37% of the total diarrheal deaths and 40% of the total diarrhea-related hospitalizations in children under five years of age worldwide[5].

2.4 Burden of Rotavirus diarrhea in India

The Indian Rotavirus Strain Surveillance Network (IRSSN) has reported that rotavirus accounts for 40% of hospitalizations due to diarrhea in children. Rotavirus is responsible for nearly 32.7 lakh outpatient visits 8.72 lakh hospitalizations, and 78,000 deaths annually in India[3].

Approximately 50% of rotavirus-associated deaths occurred in the first year of life and about 75% occurred in the first two years of life. The burden of rotavirus diarrhea and associated death varies by region, age and sex in India.[6]

Figure 2: WHO global Rotavirus deaths[5]



2.5 Modes of transmission

Rotavirus is highly contagious. Individuals suffering from rotavirus diarrhea often shed large amounts of the virus in the stool. Rotaviruses are spread primarily by the fecal-oral route directly from person-to-person or indirectly via contaminated fomites. During first episode of rotavirus infection, viruses are shed for several days in very high concentrations in stools and vomitus of infected individuals. Since infection occurs early in life, the majority of older children and adults develop some immunity against rotavirus disease.

2.6 Risk groups for Rotavirus disease

The rotavirus infections continue to persist in all settings and the proportion of diarrhea caused by rotavirus does not vary widely between developed and developing countries. It is estimated that nearly all children will be exposed to rotavirus before 3-5 years of age, regardless of where they are born. Children in low-income countries acquire the infection early during the first year of life and the median age at the primary rotavirus infection ranges from 6 to 9 months (80% occur amongst infants). In high income countries, the first episode may be delayed until the age of 2–5 years, though the majority still occur in infancy (65% occur amongst infants).

The incidence of rotavirus infection is similar in both developed and developing countries. However, more than 80% of rotavirus deaths occur in developing countries, where poverty, malnutrition and limited

access to health services exacerbate the problem. Data suggest that children in the poorest, typically rural households with the highest risk of mortality may have the earliest exposure to rotavirus. In India, studies have documented seasonal variation in rotavirus infection, with increased incidence during winter season.

2.7 Diagnosis of rotavirus infection

Clinically, it is not possible to differentiate rotavirus infection from other infectious diarrhoea and laboratory tests of stool are needed to confirm diagnosis of rotavirus infection. Various tests are available for detecting rotavirus in stool include ELISA, latex agglutination assays, strip-based tests, and reverse transcription polymerase chain reaction (RT-PCR). While ELISA and latex-based tests are widely used, RT-PCR is preferred for laboratory confirmation, serotyping and further differentiation.

2.8 Treatment

There is no specific therapy currently available to tackle rotavirus diarrhea and repeat infections are common. As with the other diarrheas, the cornerstones of rotavirus diarrhea treatment are fluid replacement with ORS and zinc treatment, which reduces the severity and duration of diarrhea. Severe dehydration may require hospitalization for treatment with intravenous (IV) fluids.

2.9 Prevention: Integrated approach

Sanitation and hygiene improvements have less impact on transmission of rotavirus diarrhea which is thought to be due to person-to person contact. The only specific intervention strategy is immunization. The rotavirus vaccine along with other interventions for prevention and management of diarrhea including exclusive breastfeeding for 6 months and continued breastfeeding with appropriate complementary feeding, vitamin A supplementation in children 9-59 months, early detection and appropriate case management of diarrhea with oral rehydration solution (ORS) and zinc (for 14 days), access to safe drinking Water, Sanitation and Hygiene interventions (WASH)), will help in reducing under five mortality due to diarrhea.

This overall approach builds on the achievement of the Millennium Development Goal to reduce child mortality *(MDG4)*, as well as to the successful implementation of the *UN Global Strategy for Women's and Children's Health and its implementation* - Every Woman Every child movement, the *Global Vaccine Action Plan (GVAP)* and the *A Promise Renewed* commitment to child survival.

Key Points

- Rotavirus is a leading cause of severe and fatal diarrhea in children under five years of age worldwide. In India, 40 percent of the children hospitalized for diarrhea are infected with rotavirus.
- An estimated 78,000 diarrheal deaths occuring annually in children in India are due to rotavirus; majority of these deaths occur in children under two years of age.
- Rotavirus is highly contagious and resilient. Nearly every child is at risk of infection, regardless of location, hygiene practices, or access to safe drinking water or sanitation.
- There is no specific treatment currently available to treat rotavirus diarrhea.
- The only specific intervention strategy for prevention of rotavirus diarrhea is immunization.

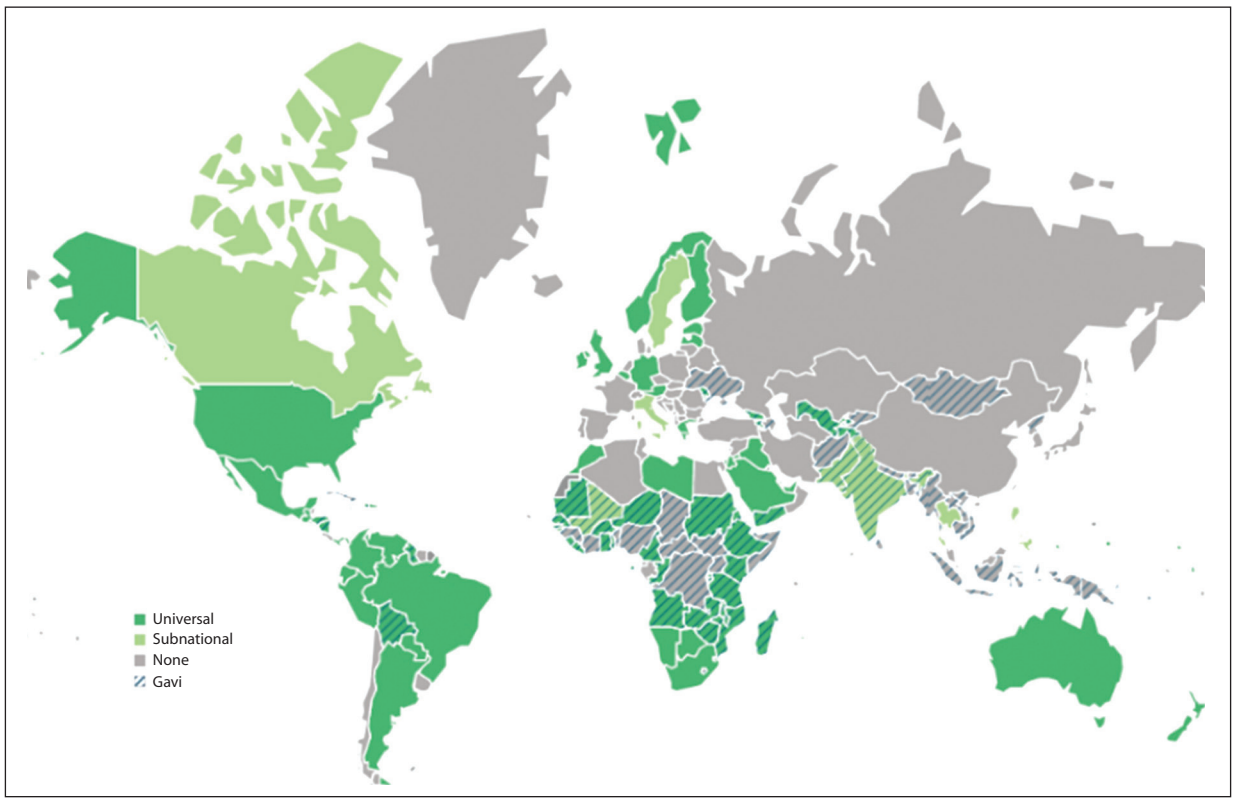
CHAPTER 3

ROTAVIRUS VACCINE GLOBAL SCENARIO

3.1 Recommendations by World Health Organization (WHO)

WHO recommends that Rotavirus Vaccines be introduced in every country's national immunization programme. As of December 2017, 93 countries have introduced Rotavirus vaccine in their national immunization programmes. This includes 86 national introductions, 3 ongoing phased introductions, and 4 sub-national introductions (Figure 3). The Rotavirus vaccines are available in more than 100 countries through the private market.

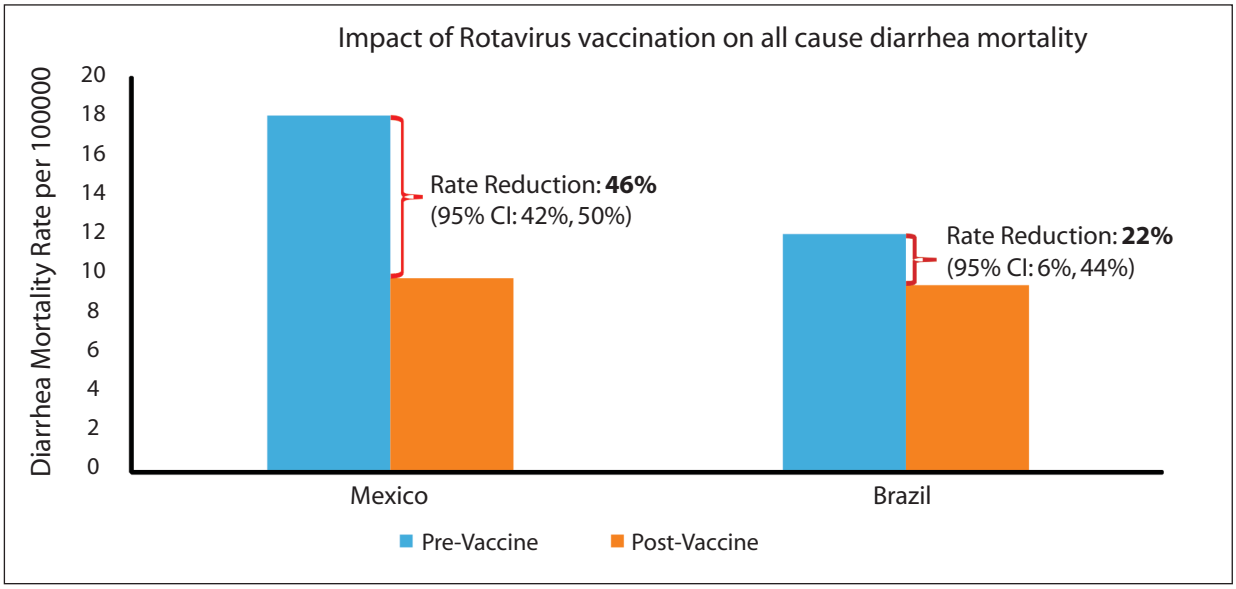
Figure 3: The 93 countries with Rotavirus vaccine in national immunization programmes[4]



3.2 Impact of Rotavirus vaccines in Public Health Programme

Globally, marked declines have been observed in hospitalizations and deaths due to rotavirus in countries that have introduced rotavirus vaccines under national immunization programmes, including Australia, Austria, Bolivia, Brazil, El Salvador, Mexico, Brazil, Nicaragua, and the United States.

Figure 4: Impact of Rotavirus vaccine introduction on all cause diarrhea mortality rates among children <5 years in Mexico and Brazil[6,7]



3.3 Currently Licensed Rotavirus Vaccines

There are four Rotavirus Vaccines available in Indian market;

- Rotasiil® (RV5), a live attenuated, oral, freeze-dried vaccine containing five viruses (Human and Bovine reassortant strains) of serotype G1, G2, G3, G4 and G9. It is manufactured by Serum Institute of India Pvt. Ltd. The vaccine is to be reconstituted before use with a diluent (Citrate bicarbonate buffer). It is given in 3 doses at 6 weeks, 10 weeks, and 14 weeks of age.
- Rotavac® (ORV116E), a live vaccine containing suspension of rotavirus 116E (G9P[11]) prepared in vero cells. It is manufactured by Bharat Biotech. It is derived from a neonatal strain isolated in India and given in 3 doses at 6 weeks, 10 weeks and 14 weeks of age. It is a liquid vaccine.
- Rotarix® (RV1), is a live vaccine (contains the RIX4414 rotavirus strain; G1P[8]) manufactured by GlaxoSmithKline Biologicals. It is given in 2 doses at 2 months and 4 months of age. It is a liquid vaccine.
- RotaTeq® (RV5), a live attenuated human bovine reassortant vaccine (containing G1, G2, G3, G4, or P1A[8]) manufactured by Merck and Co. It is given in 3 doses at 2, 4 and 6 months of age. It is a liquid vaccine.

The US Federal Drug Administration licensed Merck's RotaTeq® in February of 2006 and GSK's Rotarix® in April of 2008. The European Commission and the European Medicines Agency (EMA) licensed GSK's Rotarix® in February 2006 and Merck's RotaTeq® in June 2006. The WHO prequalified Rotarix® in January 2007 and RotaTeq® in October 2008. Both Rotavac® and Rotasiil® have been licensed by the Drug Controller General of India and are currently undergoing the WHO pre-qualification process.

3.4 Efficacy of Rotavirus vaccine

Available evidences suggest that rotavirus vaccines are most effective at preventing the most severe and life-threatening cases of rotavirus diarrhea. The efficacy of rotavirus vaccines against severe rotavirus diarrhea in India ranges from 40-60%.

The vaccine efficacy of Rotasiil® demonstrated in India is nearly 55% against the most severe and potentially life-threatening cases of rotavirus diarrhea, which represent the highest risk of dehydration, hospitalizations and deaths. The demonstrated efficacy of Rotasiil® in India appear generally comparable to the performance of RotaTeq® and Rotarix® in Bangladesh and in some African countries.[10]

As per WHO position paper (2013), there is also some evidence that Rotavirus vaccination leads to herd protection in unvaccinated older children and adults.[11]

3.5 Interaction with other vaccines

Rotavirus vaccine may be co-administered with other vaccines. Breast feeding does not significantly impair the response to rotavirus vaccines.

Key Points

- According to WHO estimates (2013) Rotavirus is responsible for 2,15,000 deaths annually in children less than 5 years of age.
- As of December 2017, 93 countries have included rotavirus vaccines in their national immunization programmes.
- WHO recommends that rotavirus vaccines to be included in national immunization programmes as part of a comprehensive approach to reduce the impact of diarrheal disease.
- The NTAGI has recommended introduction of Rotavirus vaccine in the national immunization programme of India.
- Significant declines in hospitalizations and deaths due to rotavirus and all-cause diarrhea have been observed in many of the countries that have introduced rotavirus vaccines into their national immunization programmes.
- Rotavirus vaccine is given orally with the help of a 6-ml oral syringe and prevents severe diarrhea and hospitalizations due to Rotavirus infection.
- Rotavirus vaccine will be administered to all infants along with OPV, Pentavalent vaccine and fIPV.
- Under the UIP, the upper age limit for administering the 1st dose of Rotavirus vaccine is one year.
- There are currently four licensed orally administered rotavirus vaccines available for use in India. Out of these four, two vaccines (Rotavac® and Rotasiil®) are used in UIP in India. These vaccines have been shown to be safe and effective in large-scale clinical trials.

CHAPTER 4

ROTAVIRUS VACCINE IN INDIA

4.1 The Rotavirus Vaccine in UIP

Based on recommendation by the National Technical Advisory Group on Immunization (NTAGI), the Ministry of Health and Family Welfare (MoHFW), the Government of India (GoI) decided to introduce Rotavirus vaccine in the Universal Immunization Programme (UIP) in a phased manner. An oral, liquid RVV has been successfully introduced in 9 States namely Haryana, Himachal Pradesh, Andhra Pradesh, Odisha, Rajasthan, Madhya Pradesh, Assam, Tripura and Tamil Nadu. Each dose of this vaccine is of 5 drops and is administered at 6, 10 and 14 weeks of age.

The current operational guidelines refers to introduction of a new type of oral, freeze dried Rotavirus vaccine that needs to be reconstituted before administration. Each dose of the vaccine is of 2.5 ml and is administered with the help of a 6-ml oral syringe. Like all other vaccines under the UIP, this new type of RVV will also be supplied free of cost by the Government of India.

4.2 Presentation

- Rotavirus vaccine is a live attenuated, heat stable, oral freeze-dried vaccine, and is available in 2 dose vial which must be reconstituted before use with the supplied diluent (citrate bicarbonate) only.
- Each dose is of 2.5 ml.
- The carton pack for 2 dose vial contains 50 vials (100 doses).
- It is a lyophilized vaccine.
- After reconstitution the vaccine is pinkish in colour and may sometimes change to orange or light yellow. The change in colour does not impact the quality of the vaccine.
- One vaccine vial is supplied with a diluent vial, an adapter for reconstitution and two 6 ml oral syringes.
- **Reconstituted Rotavirus vaccine vial can be used up to a maximum of 4 hours after reconstitution.**
- **It is mandatory to write date and time of opening of vial.**
- **Reconstitution and administration of vaccine should be done only by using the accessories (diluent, adapter and 6 ml oral syringe) supplied by the manufacturer.**

Figure 5: Rotavirus vaccine with diluent, syringe and adapter

Remember

- This is an oral, freeze dried vaccine which needs to be reconstituted and each dose of 2.5 ml is given with a 6 ml oral syringe

DO NOT INJECT

4.3 Storage

- Rotavirus vaccine should be stored at $+2^0$ to $+8^0$C at all levels.
- It should be stored in Walk in coolers (WIC) at GMSDs, State and Regional stores. At District and sub district stores, the vaccine should be stored in Ice Lined Refrigerators (ILR).
- In the ILR, the vaccine, should be stored at or above BCG level.

- It should be transported in cold boxes with conditioned ice-packs.
- It should be transported to session sites along with other vaccine in vaccine carrier with four conditioned ice packs.
- At the last cold chain point from where vaccines are supplied to the session sites, diluent vials should be kept between +2^{0}C and +8^{0}C in ILR. However, in case of shortage of cold chain space, diluents must be stored in the ILR between +2^{0}C and +8^{0}C at least 24 hours prior to the immunization session.
- The pre cooled diluent vials should be carried to the session site at the same temperature as the vaccine in the vaccine carrier.
- 6 ml oral syringe and adapter used for administration of the vaccine are to be stored at room temperature to avoid them from damage due to freezing. They are to be supplied to the immunization session site along with the other dry supplies outside the vaccine carrier.

The entire amount of diluent in each vial should be used to reconstitute the two dose vial of Rotavirus vaccine. The adapter and one 6 ml oral syringe will be used for the withdrawal of diluent for reconstitution. The same adapter along with the same 6ml oral syringe will then be used for withdrawal and administration of 1st dose (2.5 ml) of the reconstituted vaccine. The 2nd 6ml oral syringe with the help of the same adapter will be used for withdrawal and administration of 2nd dose (2.5 ml). The 6 ml oral syringes supplied with the vaccine is strictly for the oral administration of the reconstituted Rotavirus vaccine. These oral syringes are not to be used for injecting the Rotavirus vaccine or any other vaccine/drug.

4.4 Storage volume

Each dose of Rotavirus vaccine, occupies 10.5 cm^3 of cold chain space and with diluent, it requires 21.1 cm^3 of cold chain space.

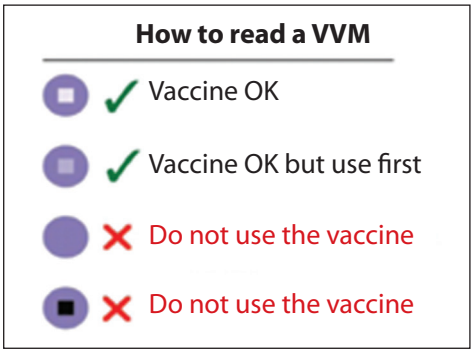
4.5 Vaccine vial monitor

This is a time -temperature sensitive label that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.

The interpretation of the VVM is similar to the other vaccines in UIP. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the outer circle, the vaccine can be used. As soon as the colour of the central square is the same or darker than the outer circle, the vial should be discarded.

This new type of Rotavirus vaccine has a Vaccine Vial Monitor-Type 30 (VVM 30).

Figure 6: VVM on RVV vials



4.6 Vaccination schedule, dosage and route of administration

Rotavirus vaccine is to be administered orally in 3 doses at 6, 10 and 14 weeks along with the other UIP vaccines. No booster dose of rotavirus vaccine is recommended. The immunization schedule following the introduction of the Rotavirus vaccine is given below:

Table 1: Updated schedule including Rotavirus vaccine

Age	Immunization schedule
At birth	BCG, OPV-0, Hep B birth dose
6 weeks	OPV-1, RVV-1, Pentavalent-1, fIPV-1, PCV-1##
10 weeks	OPV-2, RVV-2, Pentavalent-2
14 weeks	OPV-3, RVV-3, Pentavalent-3, fIPV-2, PCV-2##
9-12 months	Measles / MR**-1, Vit A*, JE-1#, PCV-B##
16-24 months	DPT-B1, OPV-B, Measles/ MR**-2, JE-2#
5-6 Years	DPT-B2
10 years	TT
16 years	TT
** Vitamin A to be given every 6 months till five years of age.* *# JE vaccine given in selected endemic districts.* *## PCV given in selected districts/states* *** MR introduced in select states*	
BCG: Bacillus Calmette-Guerin; **DPT:** Diphtheria-Pertussis-Tetanus; **HepB:** Hepatitis B; **Hib:** Haemophilus Influenzae type b; **JE:** Japanese Encephalitis; **MR:** Measles Rubella; **OPV:** Oral Polio Vaccine; **TT:** Tetanus Toxoid; **fIPV:** fractional Inactivated Poliovirus Vaccine, **RVV:** Rotavirus Vaccine, **PCV:** Pneumococcal Conjugate Vaccine	

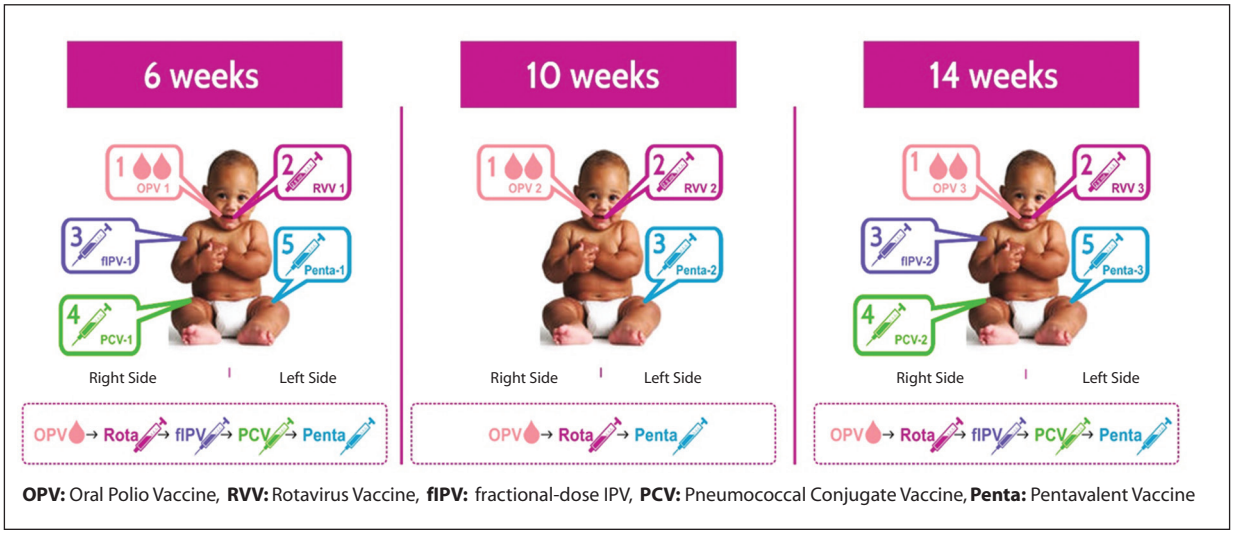
Each dose of the Rotavirus vaccine is 2.5 ml. It is to be given orally at 6, 10 and 14 weeks, The upper age limit for administering the 1st dose of Rotavirus vaccine is 1 year.

The preferred sequence for administration of vaccines to a child after introduction of RVV is

- **At 6 weeks:** OPV (2 drops oral) – Rotavirus vaccine (2.5 ml oral) – fIPV (0.1ml intradermal) – PCV (0.5 ml IM)* – Pentavalent (0.5 ml IM) vaccine
- **At 10 weeks:** OPV (2 drops oral) – Rotavirus vaccine (2.5 ml oral) – Pentavalent vaccine (0.5 ml IM).
- **At 14 weeks:** OPV (2 drops oral) – Rotavirus vaccine (2.5 ml oral) – fIPV (0.1ml intradermal) – PCV (0.5 ml IM)* – Pentavalent (0.5 ml IM) vaccine.

* wherever applicable

Figure 7: Sequence of administration of vaccines

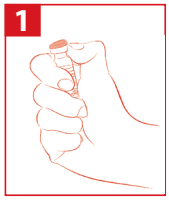


OPV: Oral Polio Vaccine, **RVV:** Rotavirus Vaccine, **fIPV:** fractional-dose IPV, **PCV:** Pneumococcal Conjugate Vaccine, **Penta:** Pentavalent Vaccine

4.7 Steps in administration of Vaccine (Rotasiil vaccine)

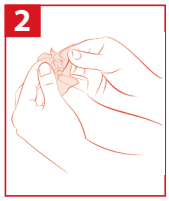
Figures below show the steps in administration of the vaccine:

1



- Take out one Rotasiil vaccine vial and one Rotasiil diluent vial from the vaccine carrier and place it on the table.
- Check and ensure that VVM placed on top of the vaccine vial is in usable stage, and the vaccine is within the expiry date.
- Check and ensure that the diluent is within the expiry date.
- Next, take out two 6 ml oral syringes and one adapter. Check and ensure that 6 ml oral syringes are within the expiry date.
- Remove the cap of the diluent vial and the vaccine vial.

2

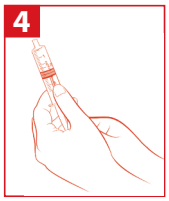


- Remove the adaptor from the packing by tearing the wrapper from the wider side of the adapter.
- **Caution:** Hold the adaptor from the body so that you do not touch the tip and the pointed end of the adapter.

3

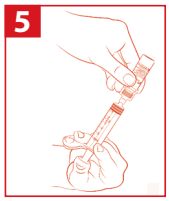
Fix the adaptor from the wider end by piercing the rubber cap of the diluent.

4



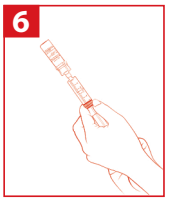
- Peel open the syringe from the plunger side.
- Draw 3 ml of air into the syringe.

5



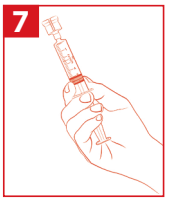
- Fix the syringe on the adaptor.
- Push the air inside the diluent vial while holding the diluent vial upside down.

6



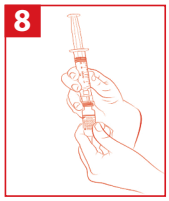
Withdraw entire amount of diluent into the syringe.

7



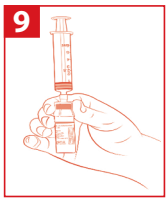
Hold the adaptor and remove the diluent vial, ensuring that the adaptor remains with the syringe containing the diluent.

8



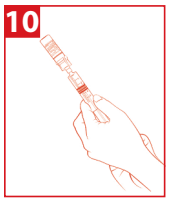
Fix this adaptor along with the syringe containing the diluent over the vaccine vial by piercing the rubber cap.

9



- Push the entire amount of diluent into the vaccine vial.
- Remove the syringe from the adaptor ensuring that adaptor remains with the vial.
- Now draw 1ml of air into the syringe.
- Attach the syringe into the adaptor and push the air into the reconstituted vaccine.

10



- Draw 2.5 ml of reconstituted vaccine.
- Separate the syringe containing vaccine, ensuring that adaptor remains with the vial.

11

- Administer the first dose (2.5 ml) of the vaccine orally to the infant.
- The administration should be slow with the nozzle pointed towards the inner cheek (buccal cavity) of the infant.
- Discard the syringe after administration.

12

- Take a fresh 6 mL oral syringe and connect it to the vial adapter on the vaccine vial.
- If there is a gap between the administration of the first and second dose, leave the syringe connected to the vial adapter so as to ensure that the vial is not open.

13

- Administer the second dose (2.5 ml) of the vaccine orally to the infant.
- The administration should be slow with the nozzle pointed towards the inner cheek (buccal cavity) of the infant.
- Discard the syringe after administration.

4.8 Phasing in

During the initial period of Rotavirus vaccine introduction, only the infants coming for the first dose of OPV and pentavalent will be administered Rotavirus vaccine. These children will be given 2nd and 3rd doses in subsequent visits as per the schedule. The upper age limit for giving first dose of Rotavirus vaccine is one year. If the child has received first dose of Rotavirus vaccine within 12 months of age, subsequent two more doses of the vaccine should be given at an interval of at least 4 weeks between two doses to complete the course. There is no booster dose required for the Rotavirus vaccine.

Infants who have already received their first or second dose of OPV and pentavalent vaccine and are now coming for their second or third dose of OPV and pentavalent vaccine should not be initiated with RVV. Such infants should receive the remaining vaccines as per schedule.

4.9 Contraindication for Rotavirus vaccine administration

The conditions where Rotavirus vaccine must not be administered to the infant:

- Known or documented allergic reaction to the vaccine. If any child reports or develops any sensitivity reaction inform the attendant of the child and also mention this clearly on the immunization card for the vaccinators' reference.
- History of documented intussusception or abdominal surgery or intestinal malformation.
- Known case of immunodeficiency.

In case of any doubt, opinion of Doctor/ Pediatrician is to be taken before administration. In infants with any moderate or severe acute illness, the Rotavirus vaccine administration should be deferred till recovery or as per Doctor's advice. However, if the infant has minor illnesses, such as low grade fever and upper respiratory infections (URI), the vaccine can be given.

Administration of Rotavirus vaccine should be postponed in infants suffering from moderate to severe diarrhea or vomiting requiring rehydration therapy. In such cases the vaccine can be administered after recovery from illness.

Remember

- Rotavirus vaccine is safe and can be given with other UIP vaccines.
- Mild illness such as upper respiratory tract infection or mild diarrhea is not a contraindication for Rotavirus vaccine administration.

4.10 Relationship with infant feeding

Breast feeding does not impair the response to Rotavirus vaccine. There are no restrictions on the infant's feed, including breast-milk, either before or after vaccination with Rotavirus vaccine.

4.11 Inter-changeability of rotavirus vaccines from different manufacturers

At present, there are four manufacturers of Rotavirus vaccine. Vaccines from these manufacturers differ in terms of dose schedule, volume per dose, reconstitution vs non reconstitution of vaccine, different storage temperature, etc and so they are not interchangeable. Therefore, if a child starts the schedule with a particular type of Rotavirus vaccine then the schedule should be completed with the same type.

For example, if a child has received vaccine from manufacturer 'A', then the child should complete the Rotavirus vaccine schedule using the vaccine from the same manufacturer 'A'. In some cases, parents may not know the type of Rotavirus vaccine given as they do not go to the same site for vaccination. In such cases, the vaccinator should try to ascertain the type of vaccine given earlier. If the same type of vaccine has been used earlier then the remaining doses should be given to complete the schedule. If the type of vaccine is not known/ different type of vaccine has been used then the parents should be asked to go back to the same service provider to complete the schedule. However, if the parents insist, then the Rotavirus

vaccine schedule should be started afresh from the same facility. The beneficiaries will be informed to get their Rotavirus vaccination from the same facilities where they have received first dose in order to avoid any mixing of Rotavirus vaccine from other manufacturer.

4.12 Interaction with other vaccines

Rotavirus vaccine may be co-administered with other routine childhood immunizations.

4.13 Long term protection

In general, the Rotavirus Vaccine provides protection for at least first 2 years, when the risk of rotavirus diarrhea is maximum. Current scientific evidence suggests that by the second year, most children are exposed to rotavirus and develop protective antibody. Thus, booster dose of Rotavirus Vaccine is not recommended.

4.14 Reuse of reconstituted Rotavirus vaccine vial

Rotavirus vaccine vial can be used up to a maximum of 4 hours after reconstitution. It is mandatory to write date and time of opening vial as applicable for all other vaccines. The open vial policy is not applicable on Rotavirus vaccine. All partially used vaccine vials should be sent back to cold chain point for waste management as per biomedical waste management guidelines.

As per the revised open vial policy guidelines, the partially used vaccine vials returned from the session sites are to be kept separately in the ILR for at least 48 hours or till the next session, whichever is earlier, and then should be treated as per biomedical waste management protocol.

4.15 Adverse events following Rotavirus immunization

Rotavirus vaccine has a good safety record; minor symptoms such as diarrhea, vomiting and irritability may occur in some children. In rare cases, intussusception has been associated with some rotavirus vaccines. Surveillance measures are recommended for documenting this rare serious event.

However, the introduction of Rotavirus vaccine (like any other new vaccine) may coincide with the increased reporting of AEFIs in the states and districts and increased cases of intussusception. All these AEFI cases, including that following Rotavirus vaccine administration should be reported as per the Government of India AEFI surveillance and response operational guidelines, 2015. AEFI causality assessment will inform about the potential association with Rotavirus vaccine.

Remember

- On reconstitution, date and time must be written on the vaccine vial.
- Rotavirus vaccine should not be used beyond 4 hours after reconstitution.
- Return the partially used vials to the Cold Chain Point after the session along with the other used vaccine vials.
- The partially used vaccine vials returned from the session sites are to be kept separately in the ILR for at least 48 hours or till the next session, whichever is earlier.

Key Points

- It is an oral, freeze dried vaccine.
- It has to be reconstituted with the diluent supplied with the vaccine.
- Each dose of the vaccine is 2.5 ml to be administered orally with a 6 ml oral syringe.
- Rotavirus vaccine has a VVM 30, which is used for highly heat-stable vaccines.
- Rotavirus vaccine is safe for administration with other UIP vaccines.
- The infant can be breast fed immediately after vaccination.
- Open vial policy is not applicable for Rotavirus vaccine.
- The vaccine vial once opened, should not be used beyond 4 hours.
- During the initial introduction of Rotavirus vaccine, only infants coming for first dose of Pentavalent vaccine and OPV will be started with Rotavirus vaccine schedule. Infants coming for the 2nd or 3rd doses of OPV and pentavalent vaccine will **NOT** be started with Rotavirus vaccine.
- The upper age limit for giving first dose of Rotavirus vaccine is one year. If the child has received first dose of Rotavirus vaccine by 12 months of age, subsequent two more doses of the vaccine should be given with an interval of 4 weeks to complete the course.

CHAPTER 5

OPERATIONALIZATION OF ROTAVIRUS VACCINE INTRODUCTION IN UIP

5.1 Preparedness assessment for Rotavirus vaccine introduction in India

The introduction of the vaccine should be considered as another opportunity to strengthen the overall RI service delivery in the states and districts. Introduction of any new vaccine in the programme requires meticulous operational planning at all levels, with detailed activities and timelines. This initially involves top-down macroplanning at the state level, followed by bottom-up microplanning and detailing precise logistic and financial needs for each district and sub-district, starting from the more peripheral levels and moving towards the higher levels. Timely trainings/orientation/ media briefing and information sharing with community helps in smooth launch at the level of health care service providers, mobilizers and community settings.

Rotavirus vaccine introduction plan encompasses all components, including a programme assessment at all levels to determine what is required for the introduction. The introduction plan takes into account the timelines for successful completion including vaccine supply and estimated procurement requirements. The vaccine introduction operational guidelines have been standardized for uniform understanding at all levels.

5.1.1 New vaccine preparedness assessment

The MoHFW, Government of India, has very recently developed and disseminated state and district-level preparedness assessment checklists prior to new vaccine introduction. These checklists have been developed to support the state and district programme managers in assessing critical information prior to introduction of the new vaccine. The checklists have been suitably modified for Rotavirus vaccine and the state should review preparedness before introducing the vaccine.

These checklists help in assessing and identifying strengths and weaknesses at state, district and block levels to take corrective actions for effective and successful introduction of any new vaccine in the UIP in respective states. Table 2 lists the different components incorporated in the checklists.

Figure 8: Preparedness Assessment Checklists

Table 2: Components of state & district preparedness assessment checklists for introduction of Rotavirus vaccine

Essential components	
1. Human resources vitals	9. Waste management and injection safety
2. Background information	10. Monitoring and supervision
3. RI Microplanning status	11. Adverse Events Following Immunization
4. Intensified Mission Indradhanush- Specific information	12. Mobilization
5. RI Training status	13. Advocacy and communication
6. RI Recording & reporting practices	14. Surveillance
7. Vaccine coverage and wastage	15. Cold chain maintenance
8. Vaccine & logistics management	
Additional components	
16. General impressions	17. Additional remarks/comments

5.2 Estimation of vaccine requirements

5.2.1 Estimation of vaccines needed

The annual number of Rotavirus vaccine doses needed is to be calculated based on the target population, three doses per child and wastage factor. Every beneficiary will require three doses at 6, 10 and 14 weeks. Considering vaccine wastage rate of 10% (for 2-dose vial) and buffer stock of 25%, the annual vaccine requirement can be calculated as follows:

Annual vaccine requirement (in doses) = (Number of beneficiaries X Number of doses per infant X 1.11* X 1.25)

(*Wastage Multiplication Factor is 1.11)

The number of vaccine vials needed for each level of store can be estimated by dividing the doses in each vaccine vial.

$$\text{Number of vials needed} = \frac{\text{Number of vaccine doses}}{\text{Number of doses in the vial (2 doses per vial)}}$$

Vaccine stores at all levels (state, regional, district, CHCs, PHCs, and other cold chain points) need to forecast their requirement of vaccine and logistics to ensure that the right amount of vaccines and logistics are available to vaccinate all eligible infants in a given area. Each of these levels should monitor the stock of vaccine and logistics in order to assess the lead-time and re-ordering levels.

5.2.2 Estimation of diluents needed

The estimated number of diluent vials will be same as number of vaccine vials.

5.2.3 Wastage rate and buffer stock

Rotavirus vaccine vial should not be used after 4 hours of reconstitution of the vial. As the vaccine is a 2-dose vial, it is estimated that there will be minimal wastage. Thus, wastage of 10% (wastage multiplication 1.11) is recommended.

The buffer stock recommended is 25% for the vaccine in the initial year. All efforts should be made to minimize vaccine wastage at all levels. The buffer stock is meant for managing sudden and unexpected shortages. The amount of buffer stock recommended is generally 25% of the annual requirement.

$$\text{Wastage rate} = \frac{[(\text{Doses issued}) - (\text{doses administered to children})] * 100}{(\text{Doses issued})}$$

Table 3: Summary wastage permissible for all vaccines in routine immunization

Vaccine	Maximum acceptable wastage
BCG	50% and the wastage multiplication factor for calculation is 2.0. Open vial policy is not applicable.
Measles and JE	25% and the wastage multiplication factor for calculation is 1.33. Open vial policy is not applicable.
IPV, OPV, Pentavalent Hepatitis B, DPT, TT, PCV and Rotavirus vaccine (oral freeze dried vaccine).	10% and the wastage multiplication factor is 1.11. Open vial policy is applicable for vaccines under this category except Rotavirus vaccine (oral reconstitution vaccine) for which open vial policy is not applicable.

5.2.3 Assessing the cold chain space and inventory

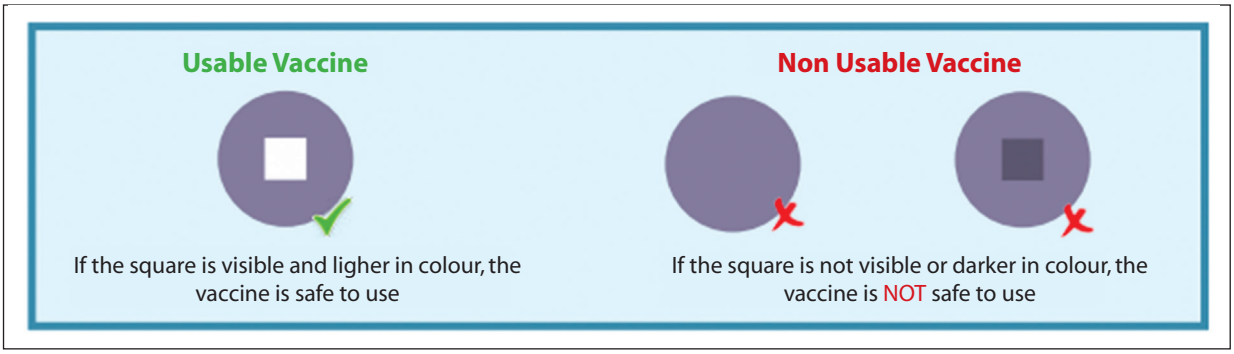
The cold chain infrastructure in India is a wide network of cold chain stores consisting of government medical supply depots (GMSD), state vaccine store, regional/divisional vaccine stores, district vaccine store and the last cold chain point at the PHC/CHC. As the RVV is supplied in a two dose vial so substantial cold chain space is required. The Districts and States must review the cold chain space requirement at different levels to ensure that adequate space is available to accommodate the Rotavirus vaccine. The cold chain inventory should be regularly reviewed and status of the same should be updated in the National Cold Chain Management Information System (NCCMIS).

Each dose of Rotavirus vaccine, occupies 10.5 cm^3 of cold chain space and each dose of diluent occupies 10.6 cm^3. Therefore, 35 cm^3 of additional cold chain space and with diluent 70.3 cm^3 would be required per infant at a cold chain point.

(Note – Net Storage Volume = 1.11 X volume of each dose,
Storage volume required per target = Net Storage Volume X no. of doses per target)

5.2.4 Cold chain monitoring

Figure 9: Reading vaccine vial monitor



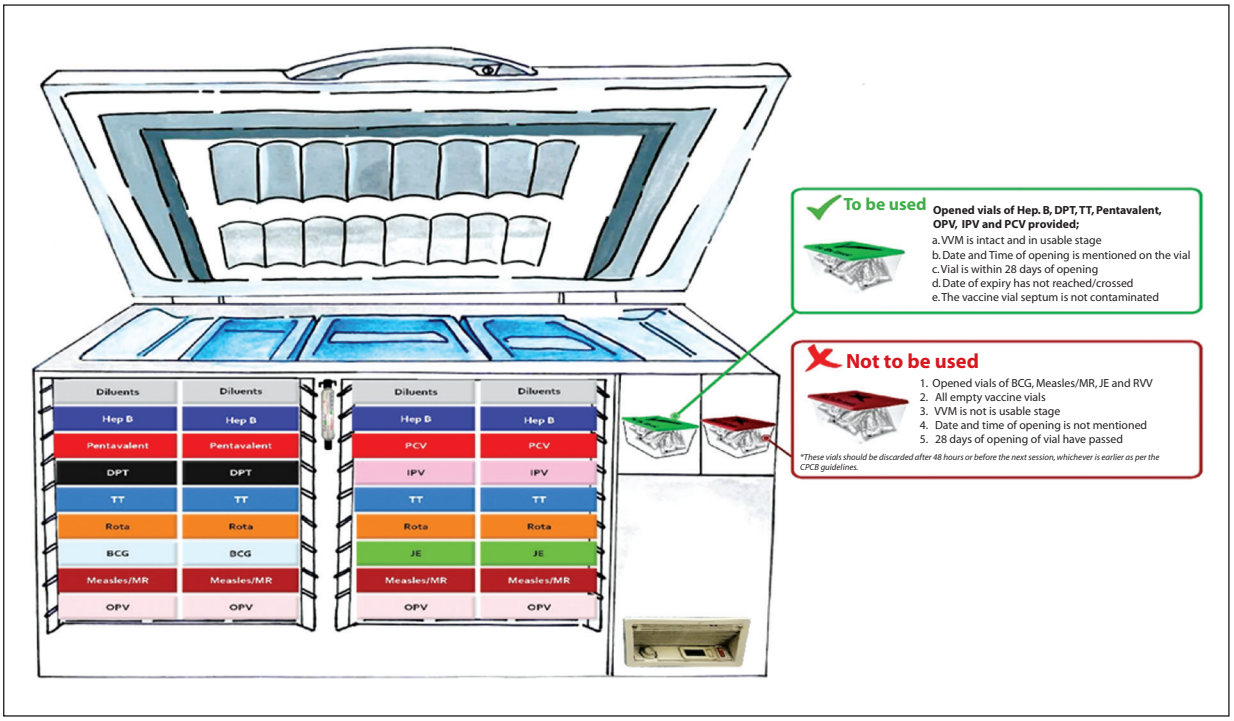
The heat impact on vaccines is cumulative. Proper storage of vaccines and maintenance of the cold chain during storage and distribution are essential to prevent the loss of potency. Once a vaccine loses its potency, this cannot be regained. Damaged vaccines should be discarded according to the guidelines.

All Rotavirus vaccine vials have a vaccine vial monitor (VVM). The VVM registers cumulative heat exposure. Before use, check the VVM on each vaccine vial. If inside square is the same colour, or darker than the outer circle, do not use the vaccine.

5.2.5 Vaccine storage

To ensure efficacy of the vaccines, proper storage and packing are essential. In top-opening ice lined refrigerators (ILRs), Rotavirus vaccine vials are to be stored along with or above the BCG vials as shown in the figure 10.

Figure 10: Vaccines/diluents storage in the ILR

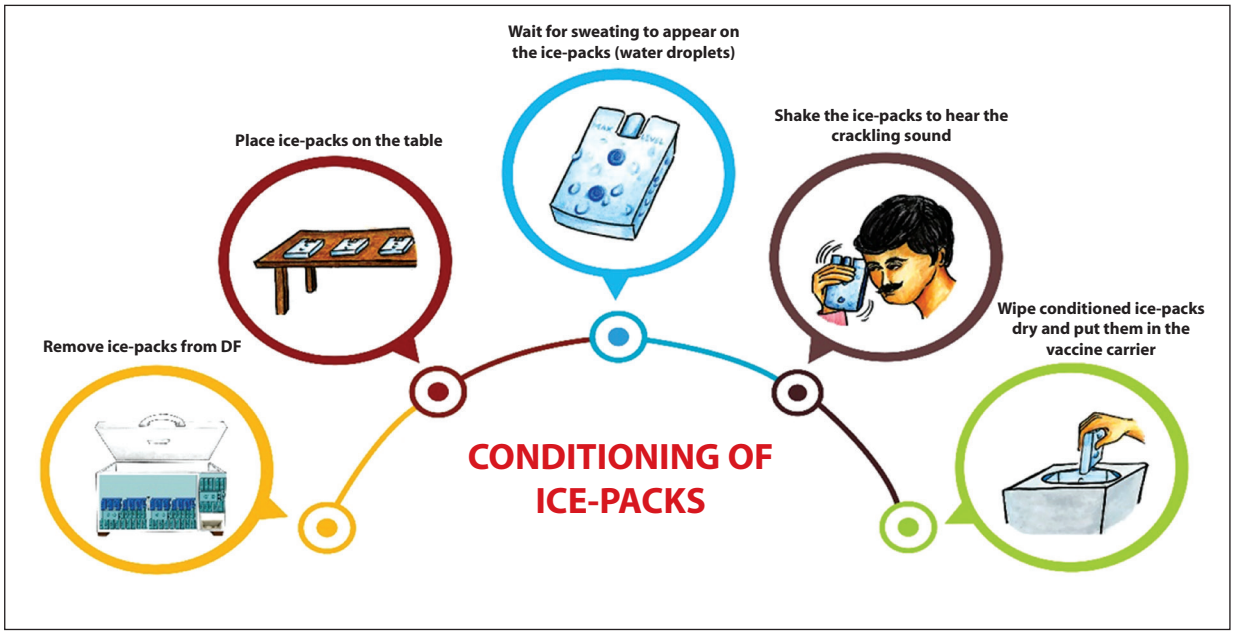


5.2.6 Conditioning of ice packs for sessions

When ice packs are taken out from the Deep freezer, they are usually at a temperature between -15^{0}C to -20^{0}C. They need to be kept at room temperature for a certain period of time to allow the temperature at the core of the ice pack to rise to 0^{0}C. This process is called "conditioning" (Figure 11):

- At start of session day, take all the frozen ice-packs you need from the Deep freezer.
- Lay these out on a table leaving a 5-cm space all round each icepack.
- Lay out icepacks, preferably in single rows but never in more than two rows.
- Check to see if ice inside the icepacks has begun to melt and some condensation, or droplets of water appears on the surface of ice packs.
- Shake the icepacks and listen for the sound of water.
- An ice pack is adequately "conditioned" as soon as beads of water cover its surface and the crackling sound of water is heard on shaking it.
- Conditioning is done to prevent freezing of the freeze sensitive vaccines.

Figure 11: Process of conditioning of ice packs



5.2.7 Rotavirus vaccine stock management (inventory control)

The inventory system should ensure that units with the nearest expiry date are used first in a system known as EEFO (early-expiry, first-out). Expiry date should always be checked whenever a vial is opened. Never use vaccines beyond the expiry date.

CHAPTER 6

PREPARING HEALTH STAFF

The successful introduction of Rotavirus vaccine will largely depend upon the quality of training conducted for all levels of health functionaries. Health-care providers are not only responsible for handling and administering the vaccine but are also a major source of information for parents and the community. A good training gives confidence to the health workers to introduce new vaccines.

All sessions must be interactive and use the adult learning methodology. Methodology should include PowerPoint presentations, role plays, exercises and interactive discussions. At district/ sub district level, each batch should not have more than 40 participants. The number of batches is to be planned according to the number of different health staffs engaged in the district/ sub district. The trainers should carefully listen to the feedback from the trainees and clarify the queries.

Health-care personnel who require training include district immunization officers (DIOs), medical officers (MOs), IEC officer, cold chain handlers, supervisors, data managers, ASHA coordinators and frontline health workers. A separate training session should be organized for ASHAs and AWWs for effective community mobilization. The officials and staff of the Department of Women and Child Development also need to be oriented at the same time. In addition, plans should be drawn up to orient the faculty of Pediatrics and Preventive and Social medicine departments in medical colleges as well as professional bodies (IAP, IMA) involved in immunization service delivery. The doctor, pediatrician and vaccinators at private facilities receiving vaccine from the public health system should also be oriented.

Remember

- Rotavirus vaccine introduction trainings should be conducted as per guidelines.
- The trainings for Rotavirus vaccine introduction should not be clubbed/ tagged with other ongoing training or review meetings.
- All trainings will have some common and some cadre-specific messages. Key tips/messages for participants have been incorporated into respective agendas.

6.1 Training approach for Rotavirus vaccine introduction

Cascaded trainings are envisaged for building capacity of all workforce involved in routine immunization. Each state where Rotavirus vaccine is to be introduced is expected to conduct State ToT workshops (two day duration).

Subsequently, the trainers trained at the State ToT will conduct district-level training for block medical officers and supervisors of their district. These Medical Officers and Supervisors (including the ASHA Coordinators) will, in-turn, be responsible for training health workers, including ANMs, supervisors and cold chain handlers. The MOs and Supervisors will also orient the ASHAs and AWWs in their areas in a separate training session.

Table 4: Training plan at different levels for Rotavirus vaccine introduction

Level	Training workshops participants	Duration
State	State Officials, DIOs, MOs, Dist. IEC Officers	2 days
District	District officials, Block MO I/Cs, MOs and ASHA Coordinator from blocks	1 day
Block	ANM, LHV, Cold Chain Handlers and Block Programme/ Data Manager	4 hours
	Block ASHA Coordinator, Mobilizers (ASHA, AWW + ANM)	2 hours

In addition, every opportunity should be utilized for sensitization of any new vaccine introduction. For example, state/district task force meetings and medical officers' RI trainings are the ideal opportunities to discuss Rotavirus vaccine introduction. All RVV introduction trainings should be conducted as per the duration mentioned in the guidelines.

All RVV trainings must have a session on practical demonstration of the reconstitution and administration of Rotavirus vaccine.

Training materials have been developed based on the past experiences of new vaccine introduction and post-introduction evaluations. These will include standardized power-point presentations from operational guidelines, FAQs for medical officers and health workers on Rotavirus vaccine. These materials could be translated into the local language and be used appropriately in the states. The FAQs on Rotavirus vaccine should be widely used for dissemination of information, especially to medical officers, frontline health workers and mobilizers.

Table 5: Key instructions for health workers while administering the Rotavirus vaccine

Step 1	Check the following details of Rotavirus vaccine before opening the vial. ◆ Name of the vaccine ◆ Manufacturer name ◆ Date of manufacture ◆ Expiry date ◆ Batch number ◆ VVM status ◆ Visible damage
Step 2	Before administration of Rotavirus vaccine, confirm the age of the beneficiary ◆ Three doses of Rotavirus vaccine are to be given at 6, 10 and 14 weeks of age along with other UIP vaccines ◆ The upper age limit for administering 1st dose of Rotavirus vaccine is one year under UIP.
Step 3	Before administration of RVV, check for any contraindication. Don't give Rotavirus vaccine to infants with ◆ History of hypersensitivity to any component of the vaccine. ◆ History of uncorrected congenital malformation of the gastrointestinal tract that would predispose the infant for intussusception. ◆ Severe combined Immunodeficiency disease (SCID) as cases of gastroenteritis associated with other live rotavirus vaccines have been reported in infants with SCID. ◆ History of intussusception
Step 4	◆ Administer 2.5 ml of Rotavirus vaccine orally using the 6 ml oral syringe supplied with the vaccine. ◆ Remember this Rotavirus vaccine is an oral freeze dried vaccine, so it has to be reconstituted with a diluent supplied along with the vaccine. ◆ The entire amount of diluent should be used to reconstitute the two dose vial of Rotavirus vaccine. The adapter and one 6ml oral syringe will be used for the withdrawal of diluent for reconstitution. The same adapter along with the same oral syringe will then be used for withdrawal and administration of 1st dose (2.5 ml) of reconstituted vaccine. The 2nd oral syringe with the help of adapter will be used for withdrawal and administration of 2nd dose (2.5 ml). The syringe is strictly for oral use. Detailed steps of administration are given in page 23.
Step 5	Record the date of administration of Rotavirus vaccine on the immunization card and RCH register.
Step 6	Return the unopened and opened Rotavirus vaccine vials after the immunization session to the cold chain point as per guidelines.

6.2 Reporting and recording of Rotavirus vaccine

All recording and reporting formats with inclusion of Rotavirus vaccine should be printed well in time before introduction of the vaccine. These formats should be distributed before introduction and ensure that during health workers' training, an exercise for filling the MCP card and other formats should be conducted.

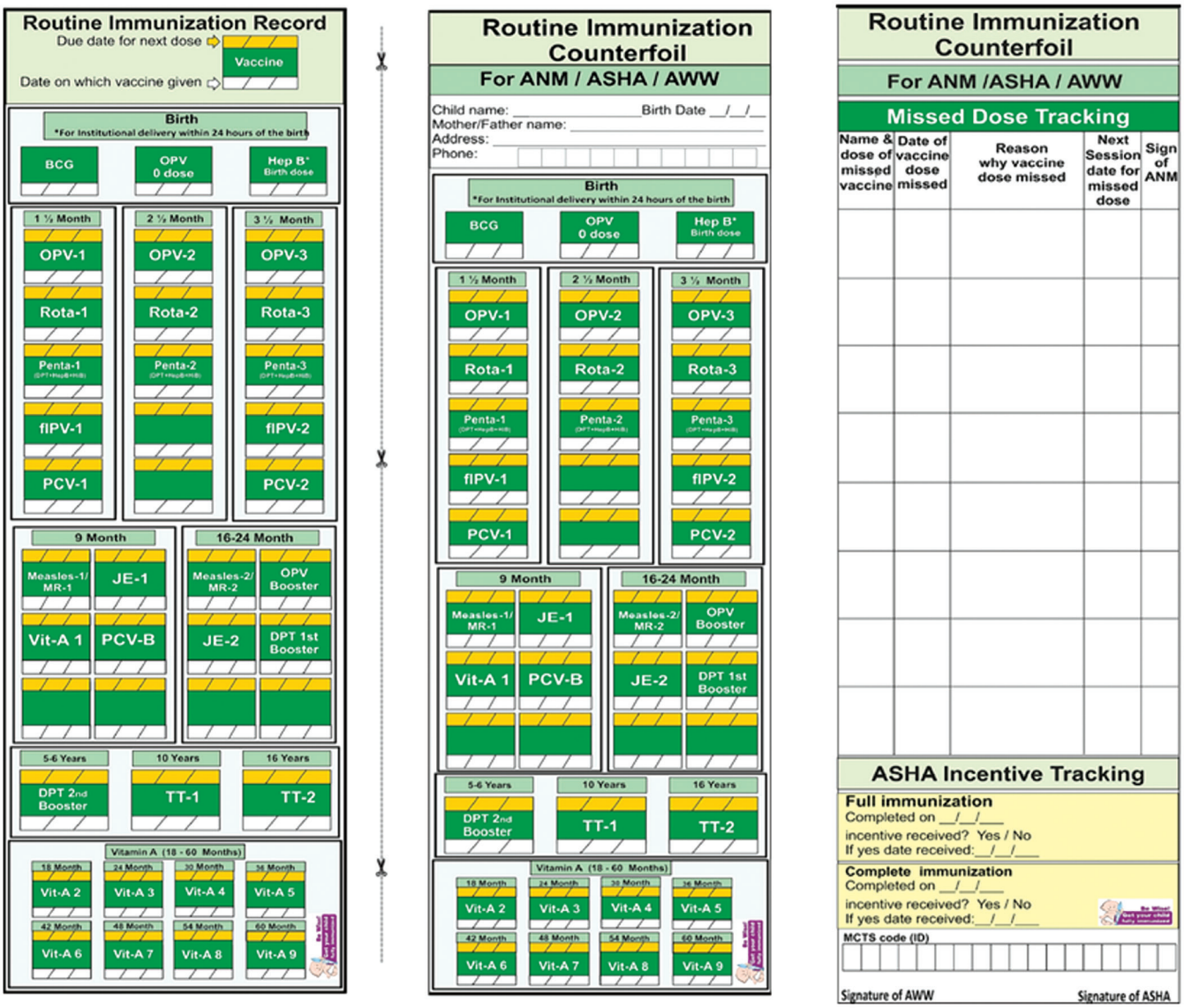
Inclusion of Rotavirus vaccine will be required in vaccine stock forms, immunization cards, due lists, tally sheets, monthly progress reports at all levels, RCH register, coverage monitoring charts, supervisory checklists and computer databases.

The electronic vaccine intelligence network (eVIN), wherever implemented, should be used to obtain real time information on Rotavirus vaccine stock and flows and also storage temperature across all cold chain points. By streamlining the vaccine flow network, eVIN contributes to strengthening health systems and also ensures equity through easy and timely availability of vaccines to all beneficiaries.

The reporting of Rotavirus vaccine coverage will be done through existing reporting mechanisms such as the HMIS (health management information system), and the RCH portal. MoHFW has updated the HMIS for capturing the Rotavirus vaccine coverage.

The modified MCP card is given below:

Figure 12: The Immunization Card



CHAPTER 7

STEPS FOR ROTAVIRUS VACCINE INTRODUCTION AT STATE, DISTRICT AND BLOCK LEVELS

The inclusion of Rotavirus vaccine in the UIP requires careful preparation and implementation at all levels. This initially involves top-down macro-planning at the state level, followed by bottom-up micro-planning, detailing precise cold chain space requirement at different levels of storage, logistics and financial needs for each district and sub-district levels.

The broad steps involved for the introduction of Rotavirus vaccine are similar to the other new vaccine introduction. The specific learning and observations related to this process in the states where early implementation of the vaccine is being planned shall inform appropriate refinement in the operational guideline.

Key Points

- Rotavirus vaccine supply shall be in 2 dose vials along with diluent vial, two 6 ml oral syringes and one adapter per vial. The vaccine needs to be reconstituted before administration.
- Assess cold chain space accordingly and if required augment the cold chain space.
- Three doses of Rotavirus vaccine are given at 6, 10 and 14 weeks of age along with other UIP vaccines. It is administered orally with the 6 ml oral syringe supplied with the vaccine.
- The vaccine is to be administered slowly with the nozzle of the 6 ml oral syringe pointed towards the inner cheek (buccal cavity) of the infant.
- The upper age limit for administering 1st dose of Rotavirus vaccine is one year under UIP in India.
- Open vial policy is not applicable for Rotavirus vaccine.
- Vaccine should only be introduced in the districts that have completed the recommended trainings.
- Cold Chain Technician to visit all cold chain points for preventive maintenance or repair of cold chain equipment at least once before vaccine introduction.

7.1 State-level Rotavirus vaccine introduction activities

The following activities should be undertaken at the state level for the successful introduction of vaccine in the universal immunization programme.

7.1.1 State task force for immunization (STFI)

- STFI should be convened at least once before the introduction to review all activities for introduction of Rotavirus vaccine in the state, including commitment and support from various departments and stakeholders.
- Issues identified for smooth introduction of the vaccine should be addressed during meetings of the STFI.
- States should make best use of lessons learnt from the polio programme to strengthen routine immunization. Opportunity like new vaccine introduction should be used to highlight issues that need attention for corrective action.
- WHO-NPSP, UNICEF, UNDP, ITSU, GHS, JSI and other key routine immunization partners involved in immunization at state and district levels are expected to provide necessary technical inputs during STFI.

7.1.2 Assessment of State preparedness for RVV introduction

The state needs to assess the preparedness using standardized checklists that have been customized for Rotavirus vaccine introduction. Data should be reviewed, compiled and reflected in the preparedness checklist. In case the state has undertaken preparedness assessment exercise recently for a new vaccine introduction then the same should be compared with the current situation to assess and identify the areas needing attention.

The state preparedness checklist with necessary annexures should be completed after review of all district level checklists and submitted to the senior state officials – Mission Director and Director, Health and Family Welfare. The assessment should be completed as per timeline. Following this the state preparedness checklist needs to be forwarded to the Deputy Commissioner (I/C- Imm), Immunization Division, Nirman Bhawan, New Delhi for review.

7.1.3 Track preparedness in districts

- Assign state observers to track planning, preparation, launch and implementation of Rotavirus vaccine in all the districts.
- The observer should visit the districts and provide oversight to activities for introduction of Rotavirus vaccine, including participation in DTFI and assessment of district preparedness as per standard checklists.

7.1.4 Strengthening routine immunization micro-plans

- All high-risk areas (HRAs) identified in polio micro plans and all additional sessions planned under Intensified Mission Indradhanush/Mission Indradhanush should be incorporated into the RI micro plans.

7.1.5 Indenting and delivery of vaccine and logistics

- Ensure availability of required quantities of Rotavirus vaccine, diluents, 6 ml oral syringes, adapters and other logistics before the introduction of the vaccine. Official communications from the state

should include the following key messages and the same should be reiterated at regular intervals.

» Rotavirus vaccine supply from Government of India will be in 2 dose vials along with diluents, 2 oral 6 ml syringes and 1 adapter per vial.

» Assess cold chain space and any deficiency need to be replenished.

7.1.6 State-level training workshop

This is a critical activity and needs timely planning and implementation. Conducting these training of trainers (ToT) workshop will create a pool of master trainers who will in turn ensure that the officials concerned at all levels are sensitized well in time prior to introduction.

The state immunization officer will be responsible for planning and conducting state-level training workshops as per timelines. Key development partners such as WHO, UNICEF, UNDP, ITSU, GHS, JSI and others will participate in the ToT and also support the states and districts in planning, sensitization of health officials and monitoring the quality of training.

The training at different levels including participants and timeline is summarized in the Table below:

Table 6: State level ToT (2 days) and media workshop (half day)

Sl No.	Participants	Facilitators	Timeline
1a. State ToT day 1	**Medical Officers** *DIO and 2 MOs per district (3 persons per district).* SIO, state CCO and other state officials including state programme manager (NHM), state IEC consultant, state ASHA coordinator, state cold chain officer, state data manager, state monitoring and evaluation (M&E) coordinator (NHM), state finance and accounts manager (NHM), State ICDS representative Regional and state representatives of WHO-NPSP, UNICEF, UNDP, JSI and other immunization partners	MoHFW officials and representatives of WHO- NPSP, UNICEF, UNDP, ITSU, GHS, NCCVMRC-NIHFW, JSI, BMGF and other immunization partners.	At least 45-60 days prior to the vaccine introduction.
1b. State ToT Day 2	*DIO + 1 District IEC Officer (nodal person) from each district for sensitization on communication planning* 1-2 representatives of partner organization dealing with IEC and media handling. Also, state officials and other key participants from Day 1	MoHFW officials, and representatives of WHO NPSP, UNICEF, UNDP, ITSU, GHS, JSI, BMGF and other immunization partners	
2.	**Media workshop (half day)** *Print and electronic media personnel (journalists)*	SIO with support from representatives of UNICEF, ITSU, JSI, WHO-NPSP, GHS. IAP, IMA and other immunization partners	In the week before launch

7.1.7 Dissemination of guidelines/ formats/IEC materials

- Disseminate all relevant guidelines and training material during training to each category of health staffs for introduction of Rotavirus vaccine.
- Ensure printing of IEC materials in local language in adequate numbers. IEC materials should be clear, attractive and easy to read. They should have focused messages and contain adequate information about the vaccine.

Ensure that all the updated reporting and recording tools including MCP card, registers, due lists, etc. are printed and disseminated before the launch. Appropriate translation in local language should be undertaken.

7.1.8 Intensify monitoring and supervision

- Intensify supervision and monitoring of trainings and programme implementation at all levels through Government functionaries and partners.
- Use standardized RI monitoring formats provided by MoHFW.

7.1.9 Communication planning

- Concentrated effort is required at the state level to build partnership for immunization. This includes involvement of all Government departments, NGOs, media, IAP, IMA and other appropriate organizations.
- The state IEC Bureau/ State IEC wing under NHM in coordination with WHO, UNICEF, UNDP, ITSU, GHS, JSI and other partners should convene a partners meeting to map resources and assign key social mobilization and communication activities.
- The state must develop a detailed communication plan for creating public awareness using various communication channels such as mass media, mid media, social media and interpersonal communication.
- Ensure timely printing and distribution of IEC materials in local language and in adequate numbers.

7.2 District-level Rotavirus vaccine introduction activities

The following activities should be undertaken at the district level for successful introduction of Rotavirus vaccine.

7.2.1 District task force for immunization (DTFI)

- DTFI should be convened once every month to steer all activities for introduction of Rotavirus vaccine in the district, including obtaining commitment and support from various departments and stakeholders. Issues identified in activities essential for smooth introduction of Rotavirus vaccine in the district should be addressed during meetings of the DTFI.
- Districts should make best use of lessons learnt from the polio programme, pentavalent vaccine and IPV introduction to strengthen RI. Make best use of vaccine introduction opportunity to highlight issues that need attention for corrective action.
- WHO-NPSP, UNICEF, UNDP, ITSU, GHS, JSI and other key partners involved in immunization at state and district levels are expected to provide necessary technical inputs during DTFI Ensure that the district refrigerator technician attend the DTFI meeting.
- Representatives of urban local bodies should be invited in DTFI.

7.2.2 Assessment of district preparedness for RVV introduction

- The district needs to assess the preparedness of the blocks using standardized checklists. The qualitative and quantitative block /planning unit data should be compiled and reflected in the district preparedness checklist.
- In case the district has undertaken preparedness assessment exercise recently for any new vaccine introduction then the same should be reviewed to visit the areas needing attention for Rotavirus vaccine introduction.

- The district preparedness check list with necessary annexures should be completed and submitted to the senior district officials – District Magistrate and Chief Medical Officer.

7.2.3 Track preparedness in blocks

- Senior district health officials have to be identified and deployed to visit and provide oversight to activities for introduction of Rotavirus vaccine in all blocks and urban areas, including participation in DTFI and assessment of district preparedness using standard checklists.
- Special focus should be made to monitor RVV introduction activities in the identified Intensified Mission Indradhanush/Mission Indradhanush districts.

7.2.4 Strengthening routine immunization micro-plans

All high-risk areas (HRAs) identified in polio microplans and all additional sessions planned under Intensified Mission Indradhanush/Mission Indradhanush should be incorporated into the RI microplans.

7.2.5 Indenting and delivery of vaccines and logistics

- Ensure availability of required quantities of Rotavirus vaccine, diluents, 6 ml oral syringes, adapters and other logistics before introduction of the vaccine. Official communication from the district should include the following key messages and the same should be reiterated at regular intervals.
  - » All indenting forms and vaccine logistics registers need to be updated to include Rotavirus vaccine.
  - » Rotavirus vaccine supply from Government of India will be in 2 dose vials along with diluents, 2 oral 6 ml syringes and 1 adapter per vial.
  - » Assess cold chain space and any deficiency need to be replenished.
- All necessary trainings must be completed before launch of the vaccine. It is preferred that all cold chain points are visited by refrigerator mechanics at least once prior to the introduction so that necessary repairs or maintenance can be undertaken well in time.
- Monitor the frequency and outcomes of visits and share the feedback in DTFI.

7.2.6 District level training workshop

Conduct district-level training workshops to create a pool of trainers at district and block levels. The DIO will be responsible for ensuring timely completion of training as per guidelines. Key development partners such as WHO-NPSP, UNICEF, UNDP, JSI and others are expected to proactively support the district in planning, sensitization of the health staff and monitoring the quality of training.

- The district and block level pool of trainers are expected to follow the cascading approach for sensitizing the health work force at district and block levels. These include training of identified block/urban planning unit MOs, cold chain handlers, data handlers, health workers and supervisors (ANMs, LHVs) and community mobilizers (ASHAs, AWWs and link workers).
- The staffs posted in big government hospitals and even medical colleges must be included.
- Details are given in Table 7.

Table 7: Details of District training workshops (1 day)

Sl No.	Participants	Facilitators	Timeline
1	**Medical officers** *Blocks to identify and nominate the names of at least 4 officials (Block MO I/Cs, MOs and ASHA Coordinator from blocks) per block/urban planning unit. Nominations to be forwarded to* DIO. Other participants to be invited include district programme manager NHM, district IEC consultant, district ASHA coordinator, district cold chain handler, district data manager, district M&E coordinator (NHM), district accounts manager (NHM)	Master trainers: DIO and 2 MOs trained at state level and partner representatives	At least 30 to 45 days prior to the vaccine introduction

7.2.7 Dissemination of guidelines/ formats/IEC material

- Disseminate relevant guidelines and training material to the participants in the workshops.
- Ensure that the district has an adequate number of printed IEC materials.
- Ensure that all the updated reporting and recording tools such as MCP cards, registers, due lists, etc. are printed and disseminated to blocks/planning units in time. Ensure that these materials are discussed and used in the sensitization workshops.

7.2.8 Assessment of cold chain capacity and functionality status

- Ensure that cold chain assessment is undertaken prior to Rotavirus vaccine launch.
- Key issues and gaps identified should be followed up and addressed at the earliest, before introduction of the vaccine.

7.2.9 Intensify monitoring and supervision

- Rotavirus vaccine introduction (trainings and programme implementation) needs to be monitored and supervised at all levels. Based on GoI guidelines intensify supervision and monitoring of RI at all levels through Government functionaries and partners. Use standardized formats provided by MoHFW.
- DTFI should use the RI monitoring data to review Rotavirus vaccine implementation at field level.
- Monitoring IEC and mobilization activities is critical for smooth acceptance of Rotavirus vaccine in the programme. Corrective action on communication monitoring data will lead to increase in coverage and help reduce dropouts and left outs in the community.

7.2.10 Communication planning

- The district health officials in coordination with other department and partner agencies should plan and conduct IEC and social mobilization activities.
- The district IEC/social mobilization plan must fortify the communication gap and ensure best utilization of available resources. Ensure timely development and distribution of IEC materials.

7.3 Block-level Rotavirus vaccine introduction activities

The following activities should be undertaken at the block level for the successful introduction of Rotavirus vaccine.

7.3.1 Revise and strengthen RI micro-plans

- All high-risk areas and migratory/non-migratory settlements identified under polio programme should be incorporated in the routine immunization microplans, using a bottom up approach.

Sessions planned in Mission Indradhanush/ Intensified Mission Indradhanush should be included in the RI Microplan.

- Ensure head count for estimation of beneficiaries by ANMs / ASHAs /AWWs for improved microplanning. Use the standardized tools. Ensure that this is a time bound activity and that it is intensively monitored by Block Medical Officer, Supervisors and partners. MO in-charge to monitor and provide oversight to this activity.
- DTFI to monitor progress.

7.3.2 Indenting and delivery of vaccines and logistics

- Ensure availability of required doses of vaccine and other logistics before Rotavirus vaccine introduction.
- Rotavirus vaccine supply from Government of India will be in 2 dose vials along with diluents, 2 oral 6 ml syringes and 1 adapter per vial.
- Assess cold chain space and any deficiency need to be replenished.
- Ensure all cold chain handlers and front line health workers are trained before Rotavirus vaccine introduction.
- Ensure that all cold chain points in the block are visited by the refrigerator mechanic at least once prior to the introduction so that necessary repairs or maintenance can be undertaken well in time. Monitor the frequency and outcomes of these visits and share the feedback in DTFI.
- DTFI are responsible to provide support for issues requiring attention

7.3.3 Block training workshops for training ANMs/ASHAs/AWWs

- ANMs/LHVs/health supervisors: The district should plan to train all the ANMs at district or block level.
- Cadre-wise attendance should be monitored closely. Provide block attendance feedback to CMO/DIO, so that the same can be shared in the DTFI.
- Mobilizers (ASHAs and AWWs) are to be trained at block level by trained block level officials. They need to be sensitized to inform caregivers to the benefits of the vaccine, so that the potential beneficiaries come forward. They need to be sensitized on the importance of follow up of dropouts and should educate caregivers on the consequences.
- WHO-NPSP, UNICEF, UNDP, JSI and other partner agencies are expected to support the Rotavirus vaccine introduction activities at block level, including monitoring the quality of training.
- Details of training at block level are given in Table 8.

Table 8: Block/Planning Unit-level training workshops

Sl No.	Participants	Facilitators	Duration	Timeline
1.	**Health workers** (ANMs, LHVs, health supervisors, cold chain handlers, data handlers)	District and block master trainers They will be supported by other trained officials such as district/block level data managers and IEC officers , district vaccine and cold chain handlers	4 hours	At least 7-10 days prior to the vaccine introduction
2.	**Mobilizers** (All ASHAs, AWWs, ANMs and mobilizers)	District and block master trainers They will be supported by other trained officials such as District/ Block ASHA coordinators, AWW Supervisors at the district level and others	2 hours	

7.3.4 Disseminate the guidelines/ formats/ IEC materials

- Ensure practical demonstration of the reconstitution and administration of the vaccine.
- Disseminate relevant guidelines and training materials to the participants during the training workshop.
- Ensure that the printed IEC materials are shared with the participants. Ensure appropriate display of IEC materials.
- Ensure that all the updated reporting and recording tools including immunization component in MCP cards, registers, due lists, etc. are shared during the training workshops.

7.3.5 Tracking beneficiaries (left outs and dropouts)

- Undertake headcount for estimation of beneficiaries by ANMs/ ASHAs/AWWs for improved micro planning, due listing and tracking.
- Use standardized tools for microplanning and estimation of beneficiaries. Ensure that it is a time-bound activity.
- State and district observers and partners should intensively monitor head count activity and share findings at all relevant platforms.
- Implementation of immunization tracking bag (one per session site). ASHA or AWW of that area to be made responsible for this. ANM to provide oversight and cross-check counterfoils to ascertain reasons for dropouts.

7.3.6 Intensify monitoring and supportive supervision

- Strengthen monitoring and supportive supervision through MOs, LHVs and health supervisors. Explain preparation of supervision plan based on priority and use of standardized formats.
- MO-in-charge and other nodal officials identified should supervise Rotavirus vaccine implementation in the routine immunization sessions.
- Blocks/planning units should be receptive to feedback from independent agencies for corrective action.

7.3.7 Communication planning

- The Block MOICs should plan IEC and mobilization activities for greater community participation. Facilitate and coordinate all available human resource such as mobilizers and NGO volunteers to create awareness and enabling environment.
- List high risk pockets and plan mobilization activities with mobilizers/volunteers.
- The communication plan must include strategic use of all communication channels such as IPC, social, print and electronic media, announcements from mosque/ temples; as also meetings with local influencers, for example community leaders, panchayat members, local practitioners, teacher to mobilize families to bring their children for immunization.
- Ensure including the names of the potential mobilizers/volunteers/ influencers in the micro plans. Distribute IEC materials well in advance as per guidelines.

7.4 Role of partner agencies

The technical and monitoring support of partner agencies such as WHO-NPSP, UNICEF, UNDP and JSI continues to be of significance in strengthening of health systems and programmes in India. The technical support provided by WHO-NPSP, UNICEF, UNDP, ITSU, JSI, BMGF, NCCVMRC-NIHFW, IPE Global, INCLEN, GHS, ICMR, PATH, CHAI, IAP, IMA, IPHA, IAPSM and others for the introduction of Rotavirus vaccine demonstrates the value addition to the process.

CHAPTER 8

STEPS FOR COMMUNICATION, ADVOCACY AND SOCIAL MOBILIZATION

8.1 Communication strategy and plan

The launch of the rotavirus vaccines in India is a critical step forward in efforts towards reducing infant and under-five mortality. A well planned communication strategy has been developed to ensure that the introduction of the new rotavirus vaccine builds upon the past experiences in improvement in vaccine coverage and reduction in IMR and U5MR. The introduction of the new type of rotavirus vaccine builds upon the existing communication strategy and approach, sensitizing the target audiences about its mode of administration, building confidence in the vaccine and sustaining demand.

8.1.1 The objectives of the communication plan

- To strengthen capacities of health workers in inter personal communication for effective delivery of rotavirus vaccine and routine immunization.
- Build the capacity of HWs for microplanning of communication activities at the community level.
- Train health workers about the correct way to administer the new rotavirus vaccine as it is introduced into the routine immunization schedule.
- Create an enabling environment for the introduction of a new vaccine through an impactful discourse around rotavirus vaccines and through positive media reporting and involvement of key stakeholders and influencers.

8.1.2 The key components of the communication strategy

- **8.1.2.1** Build a supportive and enabling environment for Rotavirus vaccine:

  - » Launch of Rotavirus vaccine at the state and district levels: Launch ceremony with participation from the state government, partners, Non Governmental Organizations (NGOs) and media.
  - » Media briefings supported with rotavirus vaccine related media kit.
  - » Release of the new rotavirus vaccine IEC materials, operational guidelines, etc.
- **8.1.2.2** Advocacy with key stakeholders such as public representatives, Government officials, public health practitioners, activists, private medical networks, doctors, religious leaders and media, etc.
- **8.1.2.3** Social mobilization for rotavirus vaccine by engaging Panchayati Raj institutions, religious leaders, social and community groups, women's groups, self-help groups, milk cooperatives, agriculture produce committees, youth clubs, NGOs, community based organizations (CBOs) and network of polio influencers.
- **8.1.2.4** Capacity development of health workers to create activation plan in the community:
  - » Training of master trainers on the new rotavirus vaccine introduction – ToTs at state/district and block levels.
  - » Cascade training of frontline workers on frequently asked questions (FAQs) related to the new rotavirus vaccine.
  - » Micro-planning and tracking of children due for rotavirus vaccine.
  - » Mothers meetings for rotavirus vaccine introduction.
  - » Influencer meetings and mosque announcements.
- **8.1.2.5** Development of robust IEC and IPC packages on rotavirus vaccine for ensuring visibility for the vaccine introduction :
  - » TV spot
  - » Radio spot
  - » Newspaper advertisement
  - » Posters
  - » Banners
  - » Leaflets
  - » Standees
  - » Info-kits for Media including factsheets and infographics in simple language.
  - » FAQs for health work force including ANM, ASHA, AWW, social mobilization network, etc.
- **8.1.2.6** Media management and crisis communication

8.2 Launch of another new rotavirus vaccine

- A successful launch of the new rotavirus vaccine will depend on mass media activities to create visibility and awareness. Alongside it will be important to build the capacity of health workers in interpersonal communication to respond to queries posed by the community.
- All communication channels should be harnessed – FM radio, television, print and social media – for wide publicity and to create increased vaccine acceptance among public.
- A well-publicized launch ceremony should be planned for the rotavirus vaccine introduction to improve general awareness about UIP and specific knowledge related to rotavirus vaccine introduction.
- The state and district task forces on immunization should steer the planning, coordination, implementation and monitoring of the programme.

- It is recommended that advocacy be conducted both before the launch of the vaccine and periodically thereafter to highlight the benefits of the vaccine and increase awareness.
- Other related Government departments, local media and NGOs should also be briefed and brought on board, so that they also spread the message and motivate the community to benefit from immunization.
- District and block level officials, especially the nominated media spokespersons should be oriented in media handling. Sustained engagement with the media is important in dispelling myths and motivating and educating caregivers and communities.

8.2.1 Preparation for launch

- Identify and brief key guests and invitees including public representatives, Government, professional bodies, media, NGO partners, religious leaders, etc.
- Identify suitable venue and date in consultation with officials concerned.
- Prepare materials for launch event from prototypes provided.
- Prepare talking points for key speakers.
- Prepare agenda for the event from the prototype provided.
- Identify photographer and equipment required for the launch.
- IEC material should be made available in ample quantities before the launch of the vaccine to raise awareness in the community. It should be clear, attractive, and easy to read, with focused messages and adequate information preferably in the local language.

8.2.2. The launch event

- Check event venue prior to the event and ensure that the equipment is in working order.
- Ensure orderly and timely conduct of the event.
- Ensure folders with materials are available for all participants.
- Ensure release of IEC materials for the rotavirus vaccine launch.
- Prepare press release based on the draft provided for print and online versions.

Launch Kit for Rotavirus vaccine

A standardized launch kit has been developed for the rotavirus vaccine introduction to be used at different levels, which will be provided to the state government containing the following:

1. Prototypes for communication materials: poster, banner, backdrop, standees.
2. Draft agenda for event
3. PowerPoint slides/other materials for use
4. Operational guidelines for Rotavirus vaccine
5. Frequently asked questions on Rotavirus vaccine
6. Draft press release

8.3 Advocacy

Advocacy is a well-defined process based on demonstrated evidence to influence decision makers, stakeholders and audiences to support and/or implement policies or actions related to the advocacy goal which in this case is to ensure that rotavirus vaccine is introduced smoothly into the routine immunization schedule and is accepted well by the community.

Advocacy with these groups is important for promoting immunization and rotavirus vaccine introduction.

- Local public representatives (MPs, MLAs, members of legislative councils, zila panchayat chairman and members, ward members for urban areas)
- Key officials of the Government and medical fraternity at the state, district and block levels:
  - » **State level:** Chief secretary, principal secretary health, Mission Director- National Health Mission, directorate of health and family welfare, state immunization officers, medical colleges, eminent private pediatricians/experts, medical institutions and professional associations (such as the IAP – Indian Academy of Pediatrics; IMA – Indian Medical Association; IAPSM – Indian Association of Preventive and Social Medicine)
  - » **District and block level:** district magistrates, chief development officers, block development officers, chief medical officers, district immunization officers, medical officers, private practitioners, etc.
- Influencers such as religious leaders, teachers, self-help groups
- NGOs and CBOs
- Media

Prepare an advocacy plan to reach out to the relevant groups using tools and materials.

Assess your existing resources and adapt them with rotavirus vaccine related messages. Document the proceedings with action points for the future. Keep the professional association focal persons informed and prepare and share IEC materials on rotavirus vaccine with IAP/IMA members.

Table 9: Indicative planning matrix for advocacy activities

S. No	Target audience	Desired action	Modalities of engagement (activities)	Tools needed/ used
1.	Policy makers and programme managers (state/district/ block)	◆ Review and support for Rotavirus vaccine introduction	◆ Meetings/ briefing sessions ◆ Launch workshop ◆ Exposure visits ◆ Debriefing on Rotavirus vaccine	◆ Advocacy kits ◆ Briefs ◆ Reports
2.	Medical officers/ institutions (IAP, IMA, IAPSM, Private doctors/experts)	◆ Orientation about Rotavirus vaccine introduction	◆ Workshop ◆ Meetings/ briefing sessions	◆ PowerPoint slides ◆ Background material on Rotavirus vaccine introduction ◆ Operational guidelines ◆ Detailed FAQs for responding to any AEFI ◆ Fact sheets ◆ Brochure
3.	Media	◆ Awareness about Rotavirus vaccine introduction ◆ Knowledge about benefits of Rotavirus vaccine ◆ Positive reporting	◆ Media briefings/ workshop	Media kit containing: ◆ Press release ◆ Background material on Rotavirus vaccine launch ◆ Compendium of messages for radio

S. No	Target audience	Desired action	Modalities of engagement (activities)	Tools needed/ used
4.	Public representatives Influencers: religious leaders, teachers, self-help groups, NGOs, CBOs	◆ Awareness about Rotavirus vaccine introduction ◆ Knowledge about benefits of Rotavirus vaccine ◆ Advocacy with the community about full immunization	◆ Meetings/ briefing sessions ◆ Community meetings	◆ Brochure ◆ FAQs ◆ Fact sheets

Advocacy Toolkit

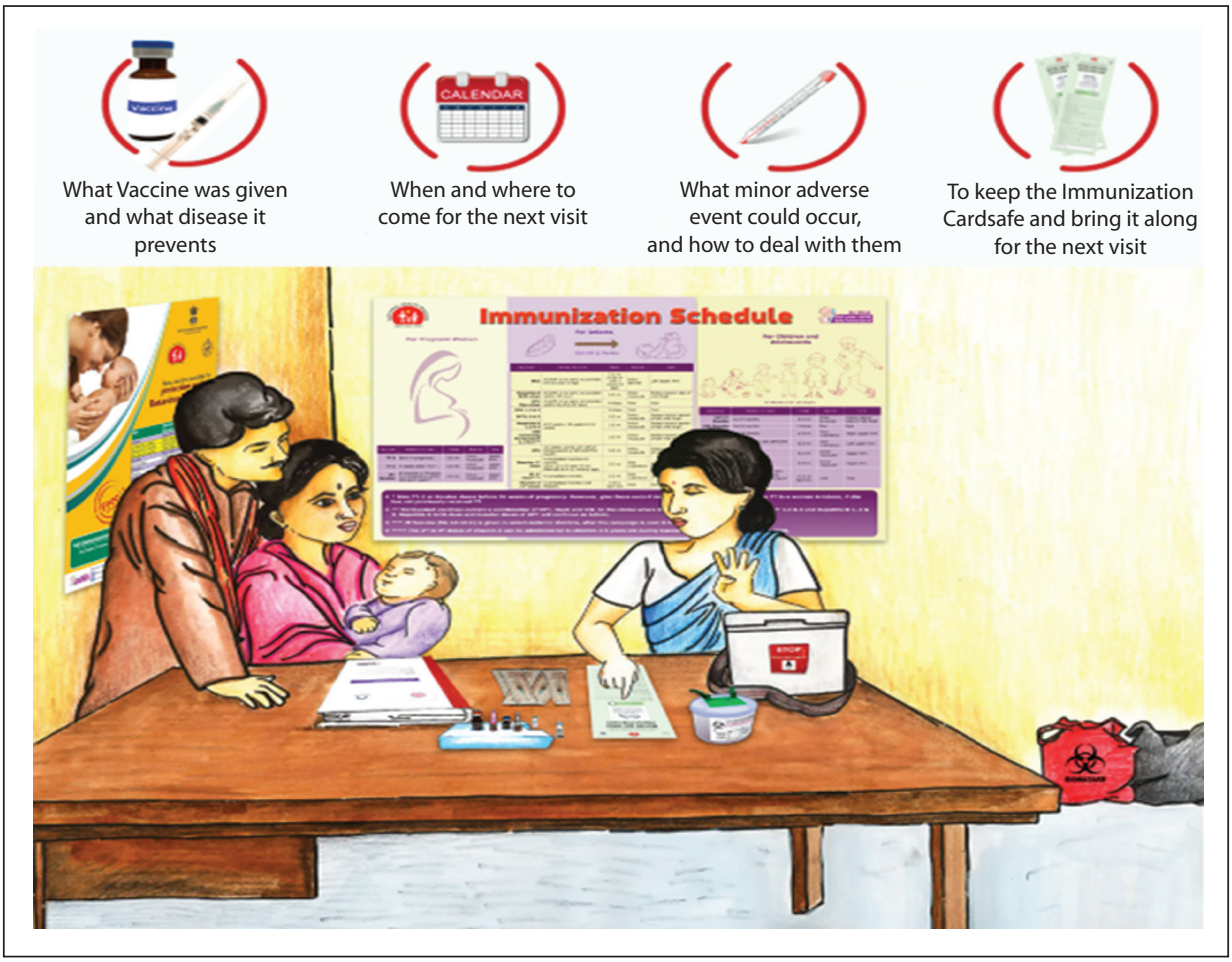
You need to develop your own toolkit using the materials that have been provided in the launch and media toolkits. Make sure that you adapt the Rotavirus vaccine related materials to the audience that you are advocating with so that correct information reaches the audience in the correct format.

8.4 Community engagement and social mobilization

- Community engagement and social mobilization is a critical activity. This entails creating dialogue with communities, answering their questions and clearing misconceptions if any. Social mobilization utilizes the influencers within the community to convince and move refusal or resistant communities/ families towards behaviour change.
- Social mobilization can make a huge difference in reaching out to all the left outs (children not vaccinated at all) and dropouts (children who started the vaccination but missed subsequent doses).
- The frontline workers and link workers are the keystone of community engagement and it is important to ensure that the auxiliary nurse midwives (ANMs), AWWs, ASHAs and community volunteers are well trained before the Rotavirus vaccine launch. Health workers, if properly trained and informed, can motivate and generate community interest in the UIP and the new vaccine. They are the main source of information for the general public. It is therefore critical to ensure that all ASHAs, AWWs and link workers are trained on key aspects of Rotavirus vaccine, including the four key messages.
- States should ensure that ASHAs and other health workers are paid their incentives and other dues on time.

8.5.1 Four key messages for care givers and families

Figure 13: Four Key Messages



8.5.2 Steps for social mobilization

1. **Preparatory phase**
   - » Update the beneficiary due list for 6 weeks-old (1½ months) infants who are due for OPV/ Pentavalent 1st dose.
   - » Preparation of due list for Rotavirus vaccine as part of the RI activities.
2. **Mobilization for RI**
   - » Mothers' meetings for RI and discussion about Rotavirus vaccine.
   - » Influencer meetings on Rotavirus vaccine introduction before launch, monthly meetings thereafter to discuss any refusal cases.
   - » Mosque/ temple/ panchayat announcements prior to RI session in the village.
   - » Mobilization of beneficiaries for RI session.
   - » Ensuring that Rotavirus vaccine given along with OPV/Pentavalent during 1, 2, 3 doses.
   - » Ensuring updating of Immunization card with Rotavirus vaccine information.
   - » Ensuring delivery of the four key messages by the FLWs including 30 minute waiting after the immunization.

8.6 IEC materials and resources for rotavirus vaccine launch

The IEC package of materials developed for the rotavirus vaccine include:

- **IEC/IPC package**
- **TV spot**
- **Radio spot**
- **Newspaper advertisement**
  - » Booth / Session site posters for Rotavirus vaccine introduction
  - » Banners
  - » Leaflet for community
  - » Standees
  - » Info kit for media

    Adapt and customize the IEC materials created at the national level to suit the requirements of the state. In the standard prototypes of IEC materials provided by the Ministry of Health and Family Welfare, incorporate state logo, local images and symbols for more receptiveness by the community.

    Translate all IEC materials of Ministry for the vaccine into local language and keep printed materials ready for use post the launch of the vaccine. Develop a simple material dissemination plan for mass media and media based on the number of session sites and health workers. Ensure that all materials are displayed prominently outside the session site and inside and at all areas of mass gathering and prominent places in the state/ district / block (e.g. market place, public offices, transit points – bus stops, railway stations, airports, highway)
- **Training resources**
  - » Training curriculum for training of frontline workers.

8.7 Media Outreach

Engaging with the media, keeping them well informed and advocating with them for the vaccine is essential to build a conducive environment for the introduction of the new rotavirus vaccine. A few steps for media outreach are outlined:

- Develop a comprehensive media plan including news media, social/digital media. A crisis communication plan is an integral part of the media plan, and needs to be well thought out and kept ready to enable ease of timely and strategic response in case of crisis.
- Prior to the launch of the vaccine, place positive stories, such as opinion articles, and interviews of local influencers to make a strong case for the new rotavirus vaccine introduction and rollout.
- Media monitoring: Regular media monitoring at the national, state and district levels is essential in media outreach preparedness. Monitoring the major print dailies, local news websites and news app groups for news on the new vaccine will provide the requisite update, intelligence and alerts on the media prior to the introduction of the vaccine, during the roll out phase and post roll out phase.
- Media briefing: It is important to ensure that the media is well briefed about the new rotavirus vaccine launch and has access to the correct information so that wrong or incorrect reporting in media is minimized.

These simple steps can be followed at the state and district level for briefing of media:

8.7.1 Around launch

- Identify spokespersons at state and district levels. These can be the SIO/CMO/District Magistrate. Ensure the spokespersons have the requisite media skills. Organize media skills training for spokespersons if necessary on information about the new vaccine. It is important to orient/sensitize these spokespersons together so that there is uniformity in understanding of the Rotavirus vaccine.
- Prepare list of state and district journalists covering health issues, with the latest contact numbers, emails and official addresses; editors of major newspapers and TV channels, radio; district-wise list of local cable operators.
- Prepare key message sheets on immunization and share with spokespersons.
- Prepare a press release from the prototype press release that has been provided in the media kit.
- Organize one day sensitization/orientation workshop for the health reporters.

8.7.2 During implementation phase

- Continue regular media advocacy after the launch event.
- Meet the editors of the leading newspapers from time to time and discuss with them the value of vaccines, disease burden and the economic burden on the family etc.
- Organize media briefing with key reporters on the new rotavirus vaccine introduction using the media kit that is provided.
- Hold media collaboration workshops; include state-level journalists.
- Keep them regularly informed of all immunization related developments through media notes.

8.7.3 Monitoring and evaluation phase

- Track reporting on the rotavirus vaccine introduction through media (newspapers, TV, radio) for tonality of reporting. Analyze the news articles and if need be reorient the journalist. Keep a track of how many positive, negative and balanced stories have appeared in a month.
- In case of negative or incorrect reporting, ensure that the reporter has access to correct information. Maintain news clippings of news reports by publication, date and placement.

Media toolkit: Prepare the media in advance for the introduction of the rotavirus vaccine by providing them adequate information, facts and standard data about the vaccine, the background of the vaccine, disease burden (global and India), efficacy of the vaccine, its cost effectiveness and impact on IMR and U5MR.

A standardized media kit has been developed for the rotavirus introduction, which will be provided to the state government for dissemination to the media during the launch ceremony/ media sensitization workshops/media briefings. The media kit contains the following:

1. Background note on the rotavirus vaccine introduction and state factsheet.
2. Frequently asked questions by media on the vaccine (Who, What, When, Where, Why and How).
3. Draft press release.
4. Format for maintaining media reports on the rotavirus vaccine.
5. Draft media response template.
6. Print the media kit in advance for dissemination to the media.

8.8 Social/Digital Media

The outreach strategy for the Rotavirus vaccine launch should include digital and social media platforms. The social media platforms like Facebook, Twitter, YouTube, and WhatsApp now has a large audience base including young populations in small towns and cities. Social media can be effectively used to disseminate information and raise awareness for the introduction of the rotavirus vaccine.

The states and districts should have social media plan for the vaccine launch which will allow stakeholders to share facts and achievements, and build awareness around the rotavirus vaccine in India through innovative content. At the national level, Twitter and Facebook will be used strategically to promote the new vaccine via the Twitter handles of the Ministry of Health, the Prime Minister, ITSU and development partners.

WhatsApp too has emerged as a popular medium which is easy to access and share information. Recently, every state health department and immunization division has an official WhatsApp group. These groups should be tapped to disseminate the positive news related to the rotavirus vaccine. The states/districts need to identify the active groups and seed information regularly through updates and photographs from the session sites, bytes from beneficiaries, local influencers, front line workers and health officials.

It is important to be vigilant about negative news, rumors about the vaccine and bringing it to the notice of the key immunization officials. Strategic responses with facts simplified need to be prepared and disseminated rapidly through the appropriate WhatsApp groups.

How to optimize the use of social media

- To map out the activities that needs to be showcased and the social media platform to be used for the same. The activities should be strategically posted keeping in mind the audience, geography and time, on the social media.
- The placement of content on social media should start one week before the launch to build up the awareness and excitement around the upcoming vaccine launch.
- All the state officials, partners and stakeholders can access to regular updates on @MoHFW_India and @vaccinate4life handle on Twitter and the Facebook page vaccinate4life. The orientation session could be held on how to use the Twitter and Facebook.
- Training sessions can be planned around the functionality of the social media tools like or share etc., on FB and Retweeting or liking a Tweet on Twitter. This would increase the social media engagement around the launch many fold.
- A list of items to go on social media to be prepared beforehand and the quality of the same should be ensured. Every item should be approved by the Ministry of Health and Family Welfare.
- Social media tracking can be done to see how much shares/likes are received and also track the negative responses if any.
- Should be prepared to deal with negative comments and posts around the vaccine launch and one person should be dedicated to handle the negative responses online. A FAQ should be prepared for the same.
- There should be live tweeting/seeding of the launch event from the location. The state social media team should be equipped to handle it.
- One should develop a WhatsApp specifically for the vaccine launch. This group will act as a platform to share the approved media materials like pictures, short videos and GiF/GFX etc. The member of this group should forward these messages further directly to other stakeholders, state officials or the beneficiaries. This will encourage further penetration of the program.

- The digital media should be targeted for placement of positive media stories or opinion articles. Should reach out to bloggers and social media influencer to endorse the vaccine launch both at national as well as regional level.

8.9 When faced with a crisis

Negative coverage in the media following an AEFI can be detrimental to the successful roll out and coverage of the new rotavirus vaccine. It is imperative to be prepared for a crisis and keep a crisis communication plan handy to deal with crisis. It is essential to deal sensitively with the media in the case of AEFI following the administration of the rotavirus vaccine. Timely and factual information to the media needs to be provided through the nominated and trained spokesperson of the district/state. Use of AEFI media communication protocol is recommended to respond systematically during a crisis.

Teams should ensure that only designated spokesperson trained in media handling communicate with the media. Appeals by respected doctors, celebrities, and religious leaders, public leaders can help to downplay negative news and build confidence in the vaccine. The states should also plan an orientation of the state and district level spokespersons prior to the introduction of the vaccine on any probable adverse effects following immunization and responses in case of AEFI

Steps to be taken during crisis:

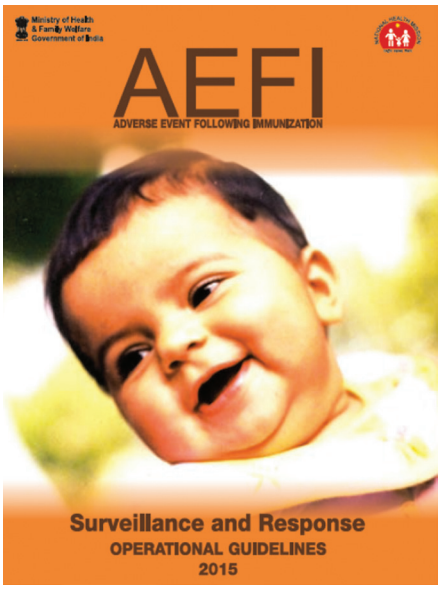
1. A core crisis communication committee, if not already constituted, should be formed with all the key state and district officials and partners.
2. To clearly draft a crisis communication plan. The plan should state in details the responsibility of the committee members during a crisis and their role.
3. There should be constant media monitoring and tracking before, during and after the launch. This will help in crisis preparedness.
4. An orientation of the state and district level spokesperson is very important prior to the vaccine introduction.
5. An immediate checklist to be prepared for the same.
6. A crisis should be dealt with both regional as well as national level.
7. Crisis communication workshop for state health officials is mandatory before the vaccine launch.
8. An elevator speech should be ready and circulated amongst the key members once there is a crisis. The plan should also identify the key spokesperson during the crisis.
9. In case of AEFI, one should strictly follow the AEFI Media Communication Protocol.
10. One can counter a crisis also through the social media platforms with the help of experts.

CHAPTER 9

ADVERSE EVENTS FOLLOWING IMMUNIZATION WITH ROTAVIRUS VACCINE

An adverse event following immunization (AEFI) is an untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. A reported adverse event can be either a true adverse event i.e. actually a result of the vaccine or the immunization process or a coincidental event which is not due to the vaccine or the immunization process but is temporally associated with immunization.

Figure 14: AEFI Standard Operating Procedures



Rotavirus Vaccines are safe and effective, and AEFIs are extremely rare. However, the health system has to be prepared for managing AEFIs. Any adverse events and other problems related to the vaccines, such as administering the vaccines to infants who should not be vaccinated, or errors in vaccine administration should be reported as per GoI's national AEFI Surveillance and Response Operational Guidelines, 2015. Programme managers should also follow the local AEFI plan and Crisis Communications Guidelines when managing AEFIs.

9.1 AEFIs linked to Rotavirus vaccine

The following adverse events may be associated with Rotavirus Vaccines:

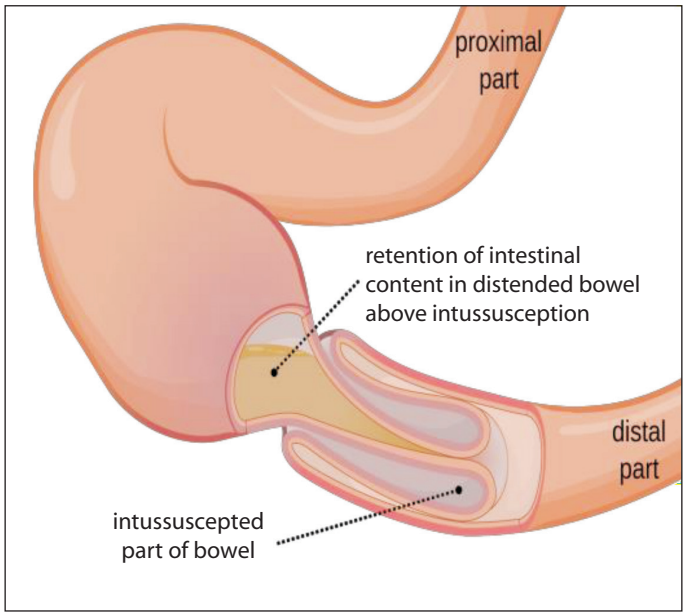
- **Minor transient symptoms:** Rotavirus vaccine may be associated with mild and transient symptoms such as vomiting, diarrhea, cough, running nose, fever, irritability and rash. These are to be treated symptomatically and recorded in the PHC AEFI register. These side effects are classified by the WHO as "safe and common side effects".
- **Gastroenteritis:** About 1 in 600 infants receiving rotavirus vaccine may have transient diarrhea and/or vomiting, mostly after the first dose. The diarrhea and/or vomiting are usually of mild in nature. These episodes may be managed with ORS and Zinc, following the standard management protocol for acute diarrhea. If notified, these cases are to be recorded in the PHC AEFI register.
- **Allergic reaction:** Rarely allergic reaction and anaphylaxis may occur with the Rotavirus vaccine. If it occurs child should be rushed to the nearest health facility and further doses should not be given. These should be managed as per standard treatment protocols and recorded in the PHC AEFI register and also reported and investigated as per AEFI guidelines.
- **Intussusception:** When one segment of the bowel becomes enfolded within another segment, it may cause acute bowel obstruction in infants and young children. Many times it is transient and resolves spontaneously.

Majority of intussusception cases occur among infants; incidence peaks at the age of 5 to7 months and more among males. (2/3:1). In majority of the cases, it is idiopathic in nature. It can be reduced by enema or surgery and if not reduced early it can lead to ischemia, necrosis and perforation (1% ≥). Ileocolic is the most common anatomical site followed by ileoileal and colocolic.

The exact incidence in India and developing countries is not known. There is limited information on the background rates of intussusception in settings of high mortality due to rotavirus gastroenteritis and the risk of intussusception following rotavirus vaccination. Global rate is estimated at 74 (range 9-328) per 100,000 infants.

Intussusception has been reported as a rare adverse event following rotavirus vaccine. As per the available literature, there is one additional case of intussusception in 20000-100000 vaccinated infants.

Figure 15: Intussusception of intestine



Clinical presentation

Typically, intussusception occurs in apparently healthy and well-nourished babies. The cases may present as:

In early stages: colicky abdominal pain with vomiting. The child cries with pain, doubles over with up-rolling of legs.

In later stages: pallor, abdominal distension, tenderness, bloody diarrhea ("currant jelly stool") and dehydration.

Although the above mentioned clinical features are expected to occur during the course of illness, these may vary from case to case. Usually abdominal pain is colicky and lasts for 1-3 minutes, with the infant appearing normal between the episodes. Vomiting may be non-bilious or bilious, lethargy or irritability may be the only presentation in some of the cases. Currant jelly stool indicates prolonged illness. In some cases if not treated on time symptom may proceed to hypovolemic shock (uncommon). Abdominal examination may reveal distension, sausage-shaped mass and tenderness with signs of peritonitis. Pallor (common), poor feeding (uncommon), diarrhea (uncommon) and abdominal distension (uncommon) may also be present.

Differential diagnosis of intussusception includes appendicitis, Meckel diverticulum, malrotation with midgut volvulus, incarcerated hernia and gastroenteritis.

It is important to note that intussusception occurs in infants without rotavirus vaccination also. The World Health Organization, the US Centers for Disease Control and Prevention (CDC), the US Food and Drug Administration (FDA), the European Medicines Agency (EMEA), the Drug Controller General of India (DCGI) and National Technical Advisory Group on Immunization (NTAGI) of India have reviewed the intussusception data and determined that the benefits of rotavirus vaccination far outweigh a potential low-level risk of intussusception.

Diagnosis

Diagnosis is usually done by ultrasound which has near 100% sensitivity and about 90% specificity. On ultrasound, the intussusception may be seen as a soft-tissue mass which is described as 'target sign'/ doughnut sign/multiple concentric ring sign.

On plain x-ray abdomen, air-fluid levels; dilated bowel loops may be seen. Presence of free intra-abdominal air may indicate intestinal perforation, a complication of intussusception.

Barium enema may reveal dilated bowel loops with meniscus sign or coiled spring sign.

In severe cases, leukocytosis and metabolic acidosis may be observed.

Referral

Any infant with clinical features compatible with suspected intussusception must be assessed immediately by a medical officer or pediatrician and referred immediately to the designated healthcare facility for management.

9.2 Intussusception Case Management Protocol

Intussusception cases may be symptomatic or asymptomatic and may resolve spontaneously. However if intussusception is suspected, the case should be immediately referred to a designated healthcare facility for non-surgical or surgical management as decided by the treating doctor.

- Non-surgical interventions

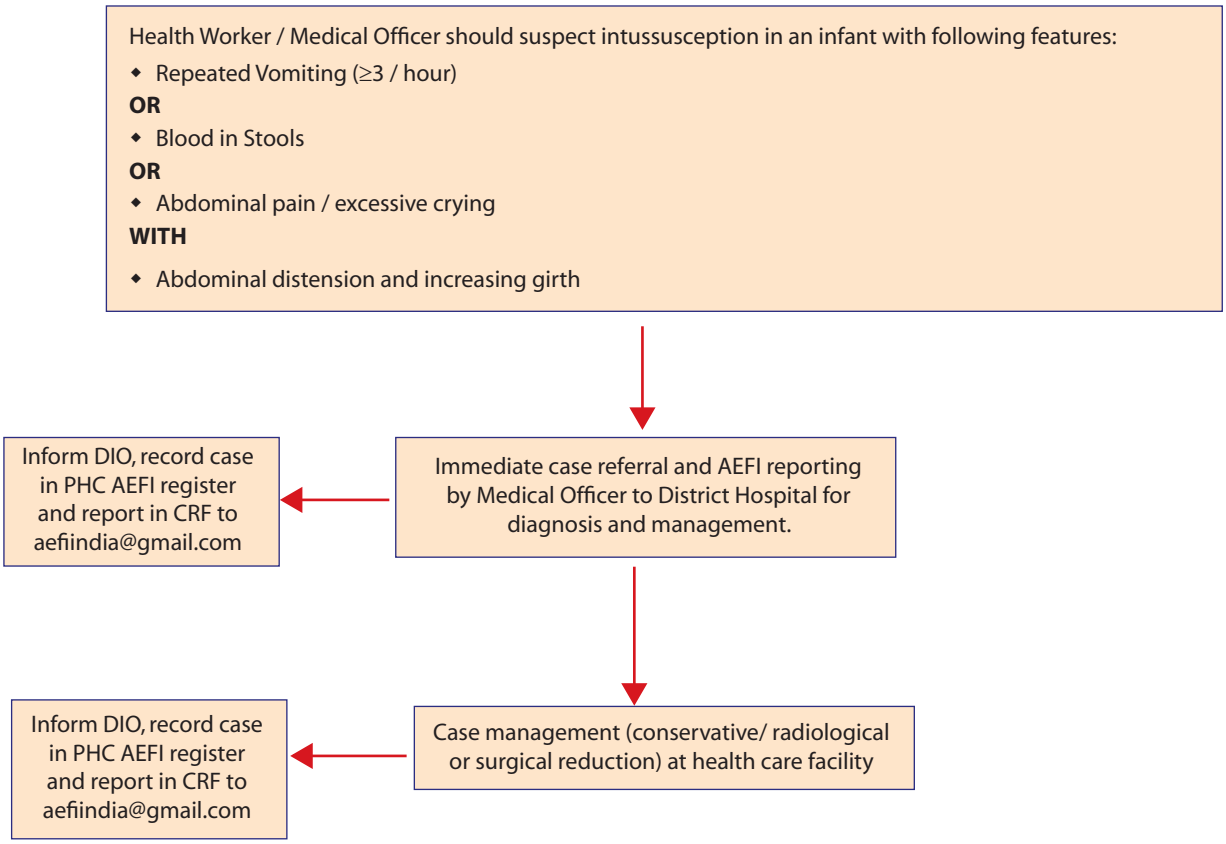
The reduction of intussusception with contrast enema techniques, especially air enema is widely used and is successful in vast majority of cases.

- Surgical interventions

Surgical reduction is indicated in the presence of refractory shock, suspected bowel necrosis or perforation, peritonitis and multiple recurrences (suspected lead point).

Before referral, careful assessment for hypovolemia and dehydration and appropriate fluid management is critical. Appropriate broad spectrum antibiotics are to be given if there are signs of infection.

Flowchart for referral and management of intussusception as an AEFI



Outcome and prognosis

If diagnosed and intervened early, the outcome is very good without any residual sequelae.

9.3 Strengthening AEFI Surveillance System

It is important to strengthen the existing AEFI surveillance system to ensure all cases are reported and investigated and assessed to know the cause of AEFI. All adverse events (minor, serious and severe) need to be recorded in the PHC AEFI register. All serious and severe AEFIs should be further reported and

investigated as per the National AEFI Surveillance and Response Operational Guidelines- 2015 (Ministry of Health and Family Welfare, GoI) using the Case reporting Form (CRF), Preliminary Case Investigation Form (PCIF), and Final Case Investigation Form (FCIF). In cases of hospitalization, all hospital records (including case records, laboratory investigation reports, discharge summaries, etc.) should be collected and submitted with the PCIF and FCIF. In cases of deaths, post mortems should be encouraged and reports sent with PCIF and FCIF. In case of deaths in which there is no hospitalization and post mortem has not been done, Verbal Autopsy Format for AEFI should be filled and sent with the PCIF/FCIF. For managing the media in case of AEFIs, the DIO and SEPIO should use the Communication Guidelines for Building Vaccine Confidence around AEFI (Government of India, 2013), the AEFI Communication Protocol and District and State Media Response Template.

Before the introduction of the rotavirus vaccine, the existing AEFI surveillance system should be strengthened through the following steps:

At the district level:

1. Ensure that the District AEFI Committee is in place and membership is updated. Call a brief meeting of the members and orient them on the immunization programme, the AEFI surveillance system and their role as member of the AEFI committee. Familiarize them with the current status of AEFI surveillance in the district, identify gaps and discuss ways to improve surveillance. In the subsequent meetings, update them on the progress made and share CRFs/PCIFs/FCIFs and get their opinion regarding the probable diagnosis in each case. Share the meeting minutes with the State EPI Officer. Ensure that the district AEFI committee meets at least once in three months and submit meeting minutes with the SEPIO.
2. Based on the analysis of the AEFI surveillance system in the district, take appropriate action to improve surveillance. Measures can include ensuring availability of PHC AEFI registers and regular recording of spontaneously notified minor, serious and severe cases, training of health workers and MOs in detecting, reporting and investigating AEFIs; encourage reporting of serious AEFIs by health workers and medical officers; making available CRFs and other investigation formats with MOs; follow up of investigations for completeness of records within stipulated timelines; etc.
3. Liaise with pediatricians, surgeons/pediatric surgeons and radiologists in the district hospitals for reporting and management of any serious AEFI including suspect intussusception cases. Ensure AEFI CRF forms and contact details of DIO/CMO are available with the department in-charge to immediately report a case and activate case management and referral protocols.

At the state level:

1. Ensure that the State AEFI Committee is in place and membership is updated. Call a two hours meeting of the members and orient them on the immunization programme, the AEFI surveillance system and their role as member of the AEFI committee. Familiarise them with the current status of AEFI surveillance in the state, identify gaps and discuss ways to improve surveillance. In the subsequent meetings, update them on the progress made and share CRFs/PCIFs/FCIFs and get their opinion regarding the probable diagnosis and causality assessment in each case. Share the meeting minutes with the Immunization Division, MOHFW, GOI. Ensure the state AEFI committee meets at least once in three months and submit meeting minutes to the Immunization Division.
2. Based on the analysis of the AEFI surveillance system in the state, take appropriate action to improve surveillance. Measures can include monitoring the functioning of the district AEFI committees in the state; identifying silent districts; collaborating with medical college in the state for investigating

AEFIs; monitor availability and use of PHC AEFI registers for recording minor, serious and severe AEFI cases, training of health workers and MOs in detecting, reporting and investigating AEFIs; ensure completeness of documentation for causality assessment; share the results of causality assessments with the Immunization Division within stipulated timelines; etc.

3. Liaise with pediatricians, surgeons/pediatric surgeons and radiologists in state hospitals, medical colleges and State chapter of IAP and IAPS (Indian Association of Pediatric Surgeons) as well as IAS (Indian Association of Surgeons) for reporting, diagnosis and management of any serious AEFI including suspect intussusception cases. Ensure AEFI CRF forms and contact details of DIO/CMO are available with the department in-charge to immediately report a case and activate case management and referral protocols.

9.4 AEFI communication plan

An Adverse Event Following Immunization (AEFI) is an unfortunate and unwanted event. Most AEFIs sound much more serious than they are, because of poor communication within the system. To handle an AEFI effectively, it is best to be prepared in advance. Internal communication is most important during an AEFI crisis. Be ready to respond promptly and effectively in case of occurrence of any AEFI. Set up a communication plan between the AEFI committee members and those working on the ground.

- All SIOs/DIOs must:
  - » Implement the district AEFI communication protocol with first and second respondents identified by name. As per the protocol, the District and State Immunization Officer may be chosen as the designated spokesperson (first respondent) for responding to media queries. In states where the CMHO/CS or the DM is the designated spokesperson, the immunization manager (DIO) provides all information to the DM/CMHO regarding the AEFI. Ensure that this spokesperson has been trained in media handling during crisis. If not, organize media-handling skills training in advance.
  - » Identify tertiary hospitals (district hospital, medical college, private hospitals) within or close to the district with facilities for diagnosing and treating cases of intussusception. Such hospitals should have facilities such as barium X-ray, ultrasound and paediatric surgery.
- All ANMs/ASHAs/AWWs and MOs must:
  - » Be sensitized to recognize and report AEFI promptly.
  - » Know what to do in the event of an AEFI and the location of the nearest AEFI treatment centre.
  - » Ensure referral mechanism to transfer an infant with possible intussusception to a facility well equipped to handle the condition.
- Develop single-page reference material for ANMs/ASHAs on what to do during an AEFI, who to contact, etc.
- Call partners meetings and discuss how messages must be communicated during an unfortunate AEFI.
- Demand for information increases from many quarters – be prepared with information!
- Coordination is crucial – take charge! Prepare a coordination plan. Constantly update it when people move out of the system and new people come in.

9.5 Media communication guidelines during AEFI

During an AEFI crisis, the media likes a quick response, accuracy and simplicity, statistics with explanation, context (part of a wider picture), comments or explanation from the highest authority, and multiple sides

of the story. The immunization programme managers may follow the guidelines given below for effective management of media during a crisis:

- Prepare a media database of journalists (print and electronic media) and regularly update.
- Identify in advance an appropriate spokesperson and share contact details of spokesperson(s) with all concerned focal points at the district, state and national levels. The spokesperson should have had the media training should be articulate and technically competent to handle the questions that arise.
- An information package may contain the following documents both in hard copy and electronic files:
  - » Frequently Asked Questions (FAQs) on Rotavirus vaccine;
  - » Fact sheet or a technical brief on Rotavirus vaccine;
  - » Fact sheet or a technical brief on AEFIs related to Rotavirus vaccine; and
  - » Contact addresses of spokespersons (experts) that media can talk to. Take prior permission and inform the expert when his/her contact numbers are shared with the media.
- Media release: The draft media release must specifically answer who, what, when, where, why, and what action is being taken.
- Mention the name and contact details of the spokesperson. The AEFI Committee may also recommend another name such as a medical expert for further details should journalists have more questions (at the end).

Important AEFI Messages

- Benefit of immunization in preventing disease is well proven.
- It is very risky not to immunize (risk of disease and complications).
- Before the introduction of vaccines, vaccine preventable diseases caused millions of death and/or disability. That situation would return without continued use of vaccines.
- Vaccines do cause some reactions, but these are rarely serious and hardly ever cause long term problems (have data ready and available to substantiate this fact).
- We have well-established immunization safety surveillance in place. Immunization safety is very important, and even the slightest suspicion of a problem is investigated.
- The AEFI is currently being investigated, but is likely to be coincidental/due to a local problem (depending on type of event), and the immunization programme must continue to keep the population safe from disease.

Important Messages related to Intussusception

- Intussusception occurs in infants and children even without having taken the rotavirus vaccine.
- The exact causes of intussusception are not known.
- Many times, intussusception episodes are transient and resolve without any intervention.
- Overall public health benefits attained by providing rotavirus vaccine through the UIP are many times higher than a very marginal increase in cases of intussusception that may occur after vaccination.

CHAPTER 10

SUPERVISION, MONITORING AND EVALUATION

A team of national and state observers shall be supervising and monitoring all activities in the prelaunch period in the states where the Rotavirus vaccine is being launched. These teams shall guide and evaluate the progress and share their findings with the state task force and national task force (Immunization division, MoHFW). It is recommended that introduction activities should start few months prior to the scheduled introduction of the vaccine.

10.1 Supervision and monitoring of implementation

Oversight of the implementation activities is crucial at all levels. Supervision should focus on bridging the gaps identified through the state and district preparedness assessment checklists.

10.1.1 National level

- Review of the state preparedness checklists and assessment of progress achieved in addressing the identified issues at regular intervals will contribute to effective implementation and also have the added benefit of strengthening the RI system in each state.
- Field visits by national observers will provide real-time information. The observers must visit the health facilities at all levels to assess the preparedness of states prior to introduction.
- The observers must share their observations with the district and state level officials for further action (if any).

10.1.2 State level

- Review of the preparedness checklists of the districts must be done by the SIO. It is recommended that a state team be formed to oversee the implementation process. Officers from various departments can also be involved in the state-level trainings to enable participation in monitoring.
- Field visits by the state immunization officer and state observers must focus on checklist findings and visit the district training sessions. Issues identified must be shared with state and district task forces for corrective actions.

10.1.3 District level

- In addition to officers of the health department, officials from Integrated Child Development Services (ICDS) department should also be involved in block-level monitoring of training.
- Child development project officer (CDPO) and local administrative officers should also be involved in monitoring the training of ASHAs and AWWs at the PHC level.

10.2 Monitoring the process of Rotavirus vaccine implementation

- Standardized data collection formats and operating procedures have been developed by the GoI to monitor the provision of RI services at immunization session sites and community level coverage of all antigens offered through UIP to detect coverage gaps.
- The introduction of Rotavirus vaccine in the UIP provides an opportunity to strengthen the overall monitoring of RI programme. The GoI mandated intensified RI monitoring strategy should be used for Rotavirus vaccine related monitoring as well.
- Appropriate information may be collected on the status of implementation through all components of RI monitoring.

10.2.1 Session site monitoring

- This captures information on vaccine supply and the availability of logistics, functioning of alternate vaccine delivery (AVD) system, immunization safety practices of ANMs, waste disposal, record keeping, inter-personal communication of service providers etc.

10.2.2 District and block level monitoring

- This provides information on coverage, vaccine stocks, wastage rates, etc.

10.2.3 Household monitoring

- This uses convenience sampling in the community surrounding RI session sites to assess the coverage of RI antigens among children under 35 months of age.

10.3 Monitoring supply of vaccines and logistics

- Available records must be examined for supply, utilization and balance of vaccines and logistics to verify whether there is a logical association between consumption of vaccines and logistics.
- If the following are found, there is a need to explore and address the reasons:
  - » The utilization of the vaccines and logistics, shows a pattern of rapid increase or decrease week after week;
  - » Doses consumed for vaccines that are provided at the same time (OPV/Pentavalent/RVV) differ widely from each other for the same period.

- If there is any mismatch between the reported number of vaccine doses and logistics consumed, the vaccinators, medical officer, store in-charge and supervising authorities concerned must be consulted to determine the reason for the variation or mismatch.

10.4 Monitoring the cold chain

- Rotavirus vaccine should be stored between +2^{0}C and +8^{0}C at all levels. Therefore, the temperature of the ILR/WIC should be monitored to ensure maintenance of cold chain.

10.5 Monitoring immunization safety

- Rotavirus vaccine is a safe and effective vaccine; however, as with any new vaccine added to the programme, adequate attention should be paid to ensure that sensitive surveillance for AEFIs is in place.
- Any AEFI should be reported in the prescribed GoI format as per AEFI Surveillance guidelines.

CHAPTER 11

LEARNINGS FROM EARLIER PHASES OF ROTAVIRUS VACCINE INTRODUCTION IN INDIA

On 26th March 2016, India became the first country in Asia to launch rotavirus vaccine in the Universal Immunization Program (UIP). In the first phase, the vaccine was introduced in four states namely Haryana, Himachal Pradesh, Odisha and Andhra Pradesh and in second phase five additional states (Rajasthan, Assam, Tamil Nadu, Tripura, Madhya Pradesh) have introduced the vaccine. The RVV used in these nine states is a liquid vaccine. Each dose of the vaccine is of 5 drops and is given at 6, 10 and 14 weeks of age.

To ensure that the benefits of rotavirus vaccine reach all the infants in the country, it is required that rotavirus vaccine is expanded to other parts of the country. However, this required a review of the current introduction in terms of the preparedness and readiness of the immunization system as well as the uptake and sustainability of the vaccine in the system. Thus, as directed by the Mission Steering Group of NHM, ICMR conducted a Programme Implementation Review (PIR) to generate evidence for the MoHFW, GoI to plan for the expansion of Rotavirus vaccine to other states. The PIR is a systematic rapid assessment of the UIP conducted in the four phase-I states with the following objectives

a) To describe the program of Rotavirus vaccine introduction in the vaccine introducer states.

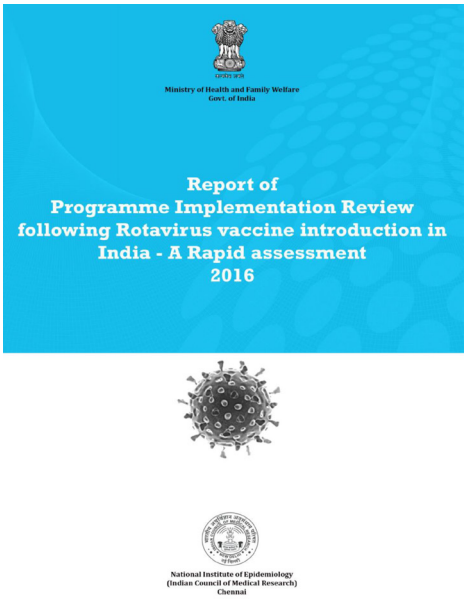
b) To review the processes involved in Rotavirus vaccine introduction in the vaccine introducer states across various implementation levels.

The PIR brought out certain good practices as well as identified areas requiring further strengthening in subsequent phases of RVV expansion. The key findings of the PIR are as follows:

- RVV cell established in all the states helped the states to follow a focused approach in presence of competing priorities like IPV introduction, Polio National Immunization days, Mission Indradhanush etc.

- With such competing priorities it is important that each stakeholder's role is well defined to ensure timely and effective implementation of each activity.
- State and district level preparatory assessment as well as cold chain assessment in the first phase helped the states, district and blocks to foresee the possible gaps and make timely arrangement to address the same. It will be important to take in to account the possibility of simultaneous introduction of PCV and MR vaccine during these assessment in subsequent phases.
- State level launch ceremonies along with positive media advocacy by key state level officials helped in creating a positive environment around RVV introduction.
- It is imperative to strengthen micro plan and plan sessions as per injection load in hard to reach and low beneficiary load areas to reduce vaccine wastage.

Figure 16: Programme Implementation Review report



- The training should follow the usual cascade model with a National and State ToT followed by district and block level trainings. All the health care workforce starting from the Medical officers to the ANMs as well as mobilisers and link workers should be trained. The feedback during the PIR showed that the availability of FAQs and single page pamphlets were useful to the workers and mobilisers which should also be provided in the subsequent phases. The training should be seen as an opportunity to provide refresher training covering all thematic areas of UIP and strengthen the overall immunization programme.
- AEFI surveillance system should be updated and strengthened in the newer RVV introducing states and districts including training on revised AEFI guidelines should be provided to service providers at all levels. The revised AEFI formats and protocols as per the AEFI guidelines of 2015, should be made available at all level of the health system.
- A detailed plan should be developed to integrate the Rotavirus and Intussusception Surveillance with existing AEFI surveillance. The surveillance data should be shared with the respective states regularly. The MOs should be apprised about the quick referral mechanism through the existing intussusception surveillance to ensure timely reporting and save infant lives.
- Apart from the communication strategies used in the first phase (posters, pamphlets) it would be useful to consider additional strategies like TV spots, radio spots etc, which focus not only on RVV but the entire spectrum of preventive and therapeutic approaches for diarrhoea control.
- During the expansion of RVV in other part of the country it will become imperative to entice positive media advocacy by conducting workshops, writing articles, Op Eds etc and sharing the success of the first phase of introduction.
- During the expansion of RVV in other states, reporting and recording tools such as MCP cards, RCH registers, due lists, tally sheets are updated and printed in adequate number well in time before the introduction of the vaccine.
- Ongoing monitoring and evaluation are cornerstones for successful implementation of a vaccination program. The existing monitoring mechanisms should be updated to include RVV and data from such should be made available to all program managers to allow them to take corrective actions. The focus should be more on supportive supervision than a mere fault finding exercise.

CHAPTER 12

ROTAVIRUS GASTROENTERITIS SURVEILLANCE AND IMPACT ASSESSMENT

The Indian National Rotavirus Surveillance Network (NRSN) was established in December 2005 to generate data on the clinical, epidemiological, and virological features of severe rotavirus disease in Indian children, using standardized protocols for enrollment and diagnostic evaluation. The hospital-based surveillance conducted between 2005 and 2009 showed that the proportion of diarrheal hospitalizations among children<5 years of age associated with rotavirus was 40%. Based on the experience gained from the first round of surveillance from 2005 to 2009 and following recommendations by the Indian Council of Medical Research (ICMR) and the National Technical Advisory Group on Immunization (NTAGI) of the Union Health Ministry, the NRSN was expanded by ICMR in a phased manner to include more hospitals in several states. The objective of this expanded network was to generate more geographically representative pan-India data that would inform the authorities in the decision making process of the need to introduce a rotavirus vaccine in the national immunization programme, track disease burden and importantly, prepare to monitor impact after introduction. From 8 hospitals in 2012, the NRSN was expanded to include 28 hospital sites across India in 2014, with the Christian Medical College (CMC), Vellore serving as the quality control and referral laboratory.

The data from the NRSN from September 2012 to June 2016 is summarized below in Table 10-13.

Table 10: Regional and Site-wise distribution of rotavirus positivity (%)

Region	Site	Number Tested	RV Positive	RV Negative	RV Positive in %
East	**Kolkata**	1282	643	639	50.2
	Midnapore	1057	568	489	53.7
	Dibrugarh	521	203	318	39.0
	Dimapur	525	220	305	41.9
	Patna	787	118	669	15.0
	Nalanda	486	43	443	8.8
	Bhubaneswar	594	316	278	53.2
		5252	**2111**	**3141**	**40.2**
West	**Pune**	784	387	397	49.4
	Mumbai	610	189	421	31.0
	Ahmedabad	388	91	297	23.5
	Surat	966	304	662	31.5
	Karad	817	291	526	35.6
		3565	**1262**	**2303**	**35.4**
South	**Vellore**	1337	392	945	29.3
	Kolenchery	899	389	510	43.3
	Trichy	562	277	285	49.3
	Hyderabad	663	164	499	24.7
	Tirupati	784	184	600	23.5
	Port Blair	1431	588	843	41.1
	Chennai	1028	317	711	30.8
	Belgaum	555	157	398	28.3
		7259	**2468**	**4791**	**34.0**
North	**Delhi***	1810	836	974	46.2
	Ludhiana	570	214	356	37.5
	Tanda	454	241	213	53.1
	Meerut	448	83	365	18.5
	Rohtak	538	161	377	29.9
	Jabalpur	316	94	222	29.7
	Bhopal	216	46	170	21.3
		4352	**1675**	**2677**	**38.5**
	Total	**20428**	**7516**	**12912**	**36.8**

** Data from two surveillance sites*

The Rotavirus positivity in cases of hospitalized acute gastroenteritis was 36.8% for the country. The positivity ranges from 34-40% in each of the North, South, East and West zones suggesting the Rotavirus prevalence may be similar throughout India.

Table 11: Age- group wise distribution of rotavirus positivity

Age (m)	RV Positive	RV Negative	Number Tested	RV Positive %
0-2	236	1157	1393	16.9
3-5	669	1581	2250	29.7
6-11	2650	3773	6423	41.3
12-23	2768	3602	6370	43.5
24-35	714	1410	2124	33.6
36-47	301	782	1083	27.8
48-59	178	607	785	22.7
Total	**7516**	**12912**	**20428**	

The Rotavirus positivity was highest in age groups of 0-11 months (< 1 year) and 12- 24 months (1-2 years of age groups), which is consistent with global trends.

Table 12: Distribution of rotavirus positivity across diarrheal disease severity categories

Disease severity	RV Positive	RV Negative	Number Tested	RV Positive %
Mild	196	516	712	27.5
Moderate	2463	5052	7515	32.8
Severe & Very severe	4856	7342	12198	39.8
Total	**7515**	**12910**	**20425***	

**3 cases Vesikari score could not be calculated.*
Nearly 3/4 (72%) of moderate and severe diarrhoeal cases were attributed to Rotavirus.

Table 13: Seasonal distribution of rotavirus cases

Season	RV Positive	RV Negative	Number Tested	RV Positive %
Dec-Feb	3239	2848	6087	53.2
Mar-May	1639	3344	4983	32.9
Jun-Aug	976	3783	4759	20.5
Sep-Nov	1662	2937	4599	36.1
Total	**7516**	**12912**	**20428**	

Rotavirus prevalence peaked in winter months with nearly 53% positivity in months of Dec- Jan. The NRSN project was completed in 2016.

Surveillance for impact assessment

As rotavirus vaccines are introduced into the Universal Immunization Programme (UIP) in India, monitoring their impact is a high priority. Reductions in child deaths and hospitalizations from rotavirus acute gastroenteritis (AGE) are anticipated, and documenting these benefits and any risks is necessary.

The rotavirus vaccines are being introduced in a phased approach across India. The rotavirus vaccine was introduced in 2016 in Andhra Pradesh, Odisha, Haryana and Himachal Pradesh. Each of the four early introducing states had at least one site that was already part of the NRSN through ICMR and CMC's networks and contacts. A new study the Rotavirus Vaccine Impact Study (RVIS) was started in 2016, under an ICMR Steering Committee. Additional hospitals which were known to admit larger numbers of children for acute gastroenteritis were identified in each of the four states.

The data on hospitalized cases of acute gastroenteritis and rotavirus positivity among them until September 2017 is presented in Table 14. However, this study will assess impact in a case control design in children who are eligible to have received the vaccine. Therefore, a formal impact analysis will be done in 2018-2019.

Table 14: Hospitalizations and rotavirus positivity for acute gastroenteritis in children less than 5 years of age until September 2017 in four phase 1 introduction states

State	Location	No. of children admitted with diarrhea	No. of stool specimens collected	Number of vaccine cards obtained	Number of rotavirus ELISA positives	Percentage RV positive
Andhra Pradesh	Kurnool	570	487	437	138	28.3
	Kakinada	31	24	22	3	12.5
	Vizag	433	299	259	50	16.7
	Tirupati	539	473	455	102	21.6
Odisha	Cuttack	1027	833	801	294	35.2
	SUM, BBSR	403	356	339	149	41.8
	KIMS, BBSR	511	434	397	116	26.7
	Hi – Tech, BBSR	820	656	570	251	38.3
Haryana	Rohtak	424	226	213	40	17.8
	Mewat	925	688	589	116	19.7
	Sonepat	416	206	197	54	26.2
	Chandigarh	960	175	160	35	20
Himachal Pradesh	Tanda	684	316	331	99	31.3
	Shimla	310	201	193	40	19.9
Total		**8447**	**5713**	**5290**	**1616**	**27.6**

Surveillance has been initiated in late 2017 in phase 2 states of Assam, Rajasthan, Madhya Pradesh and Tamil Nadu with one or more sites recruiting children hospitalized with acute gastroenteritis.

In both phase 1 and phase 2 states, surveillance is also being carried out for intussusception. The summary data from the intussusception data is provided in Table 15 below. Note that the total reports include children of all ages, including those who have not received vaccine, and the number of cases who have received rotavirus vaccine includes children who received rotavirus vaccine much before the occurrence of intussusception, and thus most cases do not fall in the risk window. Analysis of the case-control data to assess if there is any risk with the vaccine currently in use will be conducted when data on sufficient numbers of cases are collected.

Table 15: Summary of sentinel surveillance for intussusception (includes un-vaccinated cases and cases not in the risk window)

State	Location	Total number of IS cases	Number of vaccine cards obtained
Andhra Pradesh	Kurnool	12	12
	Kakinada	1	1
	Vizag	19	19
	Tirupati	14	14
Odisha	Cuttack	55	54
	SUM, Bhubaneshwar	16	16
	Kalinga, Bhubaneshwar	9	8
	Hi – Tech, Bhubaneshwar	4	4
Haryana	Rohtak	15	14
	Mewat	8	8
	Chandigarh	101	101
Tamil Nadu	CMC	3	1
	Kanchi Kamakodi	10	10
	Egmore-ICH	3	0
	Coimbatore	4	4
Pondicherry	Pondicherry	2	2
Uttar Pradesh	Lucknow	6	5
		308 (100%)	**295 (96%)**

CONCLUSIONS

- Rotavirus is an important cause of gastroenteritis in Indian children in all parts of the country.
- Rotavirus vaccine introduction has been paralleled with impact assessment study of Rotavirus vaccine for effectiveness and safety. The impact assessment process is in place in eight states that have introduced rotavirus vaccination.
- The sites chosen are appropriate for monitoring vaccine safety, because they have captured background intussusceptions prior to vaccine introduction.
- The monitoring of vaccine so far shows no reason for concern regarding effectiveness or safety. However, it will take time to recruit enough children in the age-appropriate group for vaccination to ascertain statistically significant effectiveness through a case-control design.

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NOTES


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