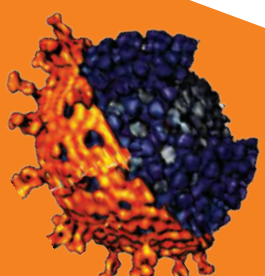
सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

Operational Guidelines

Introduction of Rotavirus Vaccine in the Universal Immunization Programme in India



Immunization Division
Ministry of Health & Family Welfare
Government of India

DECEMBER 2015

Be Wise!
Get your child fully immunized

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FOREWORD

It gives me great pleasure to present the Operational Guidelines for introduction of Rotavirus vaccine as part of the Universal Immunization Program (UIP). The vaccine is proposed to be introduced in four states to begin with, in a phased manner.

The UIP was launched in India in 1985 and since then India has made significant progress in expanding the coverage and improving the quality of routine immunization across the country. During the last few years, India has been successful in eliminating wild polio virus, has been validated for maternal and neonatal tetanus elimination, successfully scaled up pentavalent vaccine nationwide in addition to recently introducing the Inactivated Polio Vaccine (IPV) in a phased manner throughout the country.

While we take pride in these accomplishments, substantial efforts are still needed to end child deaths due to preventable causes. Diarrheal diseases are the leading cause of childhood mortality and are responsible for more than 3.3 lakh deaths of under-five children annually in India. Specifically, Rotavirus is responsible for nearly 40% of moderate to severe diarrhea in under-five children resulting in more than 1.2 lakh deaths and 4.5 lakh hospitalizations.

These deaths can be prevented through the Rotavirus vaccine. Worldwide, 79 countries provide Rotavirus vaccines to children as part of their national immunization programme. In India, Rotavirus vaccines have been in use in the private sector. However, these are expensive and therefore not affordable for a large proportion of India's population. A need was hence felt to introduce the Rotavirus vaccine in UIP to ensure that preventable deaths due to Rotavirus vaccine are addressed.

Introduction of Rotavirus vaccine under the Universal Immunization programme is a milestone achievement in expanding the benefits of vaccines to all children.

The operational guidelines are meant to enhance the capacity of the Immunization program managers at the state, district and sub-district level to operationalize introduction of the Rotavirus vaccine. I am hopeful that the document will strengthen the states in roll out of the vaccine. I commend all those who have contributed to this document for their valuable work.

(Dr. Rakesh Kumar)

Acknowledging the contribution of all partner organizations including **WHO, UNICEF, PATH, INCLEN, GHS, UNDP** and special thanks to members of the **National Expert Committee on Rotavirus vaccine.**

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
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 Social and Preventive 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
NGO	:	Nongovernmental Organization
NHM	:	National Health Mission
NPSP	:	National Polio 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
RMNCHA	:	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 EPI 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
WIF	:	Walk-In Freezers

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 *Rotavirus Vaccine* in the immunization programme in selected areas initially followed by countrywide subsequently, when the vaccine will be introduced fully in 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 14% of under-five deaths, amounting to about 3,34,000 deaths annually in India. Available data indicates that Rotavirus is responsible for nearly 40% of moderate to severe diarrhea in under-five children amounting to 4,50,000 to 8,84,000 hospitalizations, 20,00,000 outpatient visits and 1,22,000-1,53,000 deaths annually in India. 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.

In recognition of the global rotavirus disease burden, WHO has recommended inclusion of Rotavirus Vaccines in national immunization programmes 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 79 countries. In countries where Rotavirus Vaccine has been introduced, a significant reduction in hospitalization and death due to rotavirus has been documented. It is estimated that rotavirus vaccination in India could prevent 41,000 to 48,000 deaths in children under five years.

The National Technical Advisory Group on Immunization (NTAGI), Ministry of Health and Family Welfare, Government of India has recommended the introduction of Rotavirus vaccine in the country in a phased manner under the Universal Immunization Programme (UIP).

This operational guideline has been developed to facilitate smooth introduction of the Rotavirus Vaccine under UIP in India.

CHAPTER 2

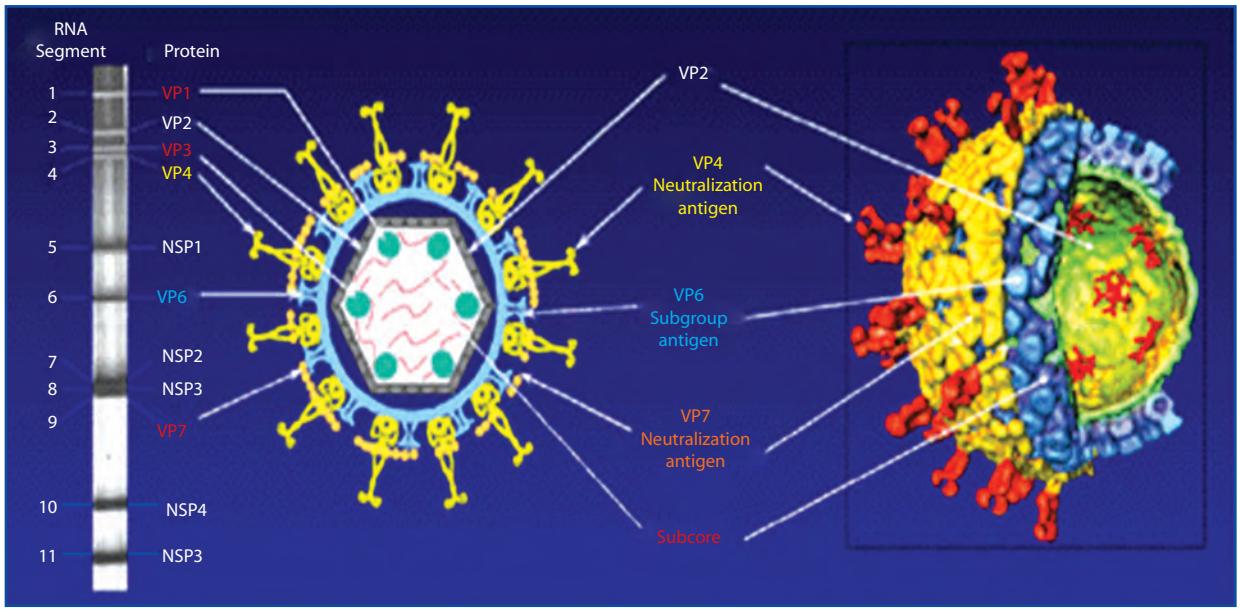
EPIDEMIOLOGY OF ROTAVIRUS DIARRHEA

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 that 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 and medical care. 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

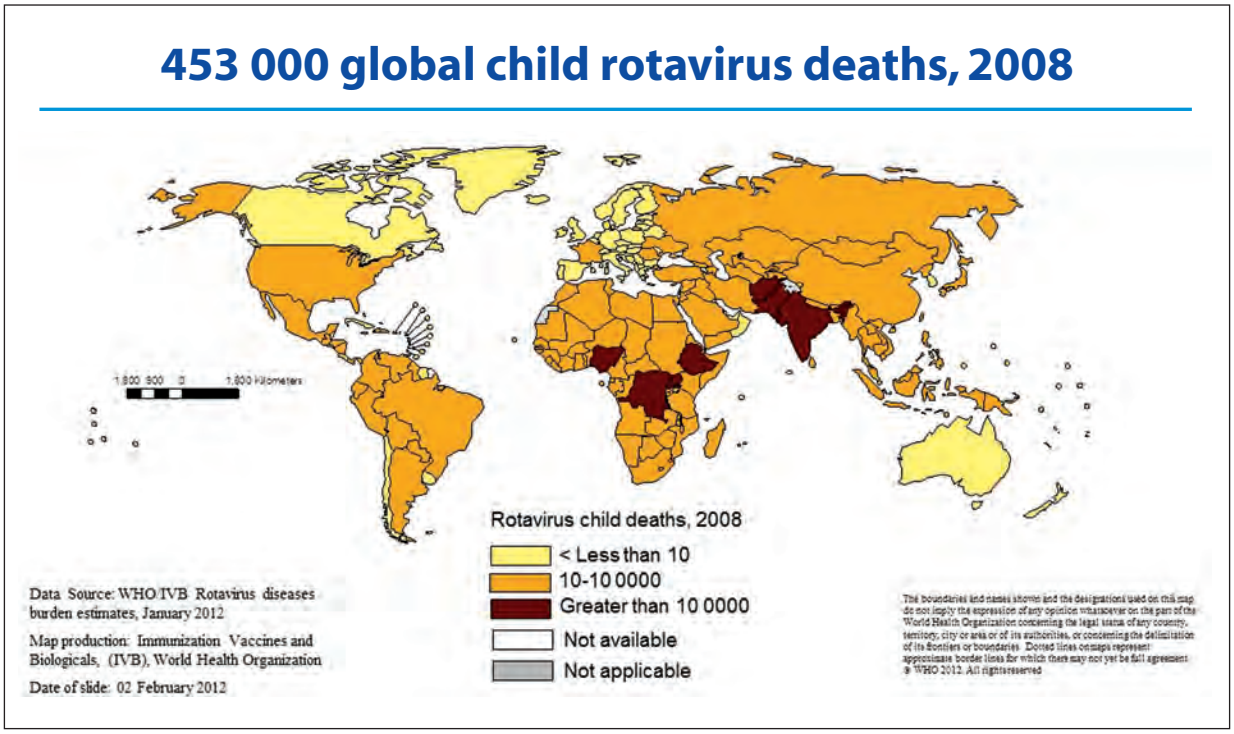
According to the World Health Organization's (WHO) (2008), rotavirus is responsible for more than 4,50,000 deaths each year in children younger than five years of age and 5% of all under-five deaths worldwide. Rotavirus is also responsible for millions of hospitalizations and clinic visits each year. 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 Africa (232,000) and Asia (188,000). More than half of these deaths attributable to rotavirus occurred in five countries - India, Nigeria, Democratic Republic of the Congo, Ethiopia, and Pakistan. India bears the highest burden accounting for 22% (98,621) of worldwide rotavirus deaths.

Rotavirus is estimated to cause 37% of the approximately 800,000 diarrheal deaths and 40% of the 9 million diarrhea-related hospitalizations in children under five years of age worldwide.

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 4,50,000 to 8,84,000 hospitalizations, 20,00,000 outpatient visits and 1,22,000-1,53,000 deaths annually in India. 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. The burden of rotavirus diarrhea has been observed to be more in central, east and north eastern region.

Figure 2: WHO global Rotavirus deaths[1]



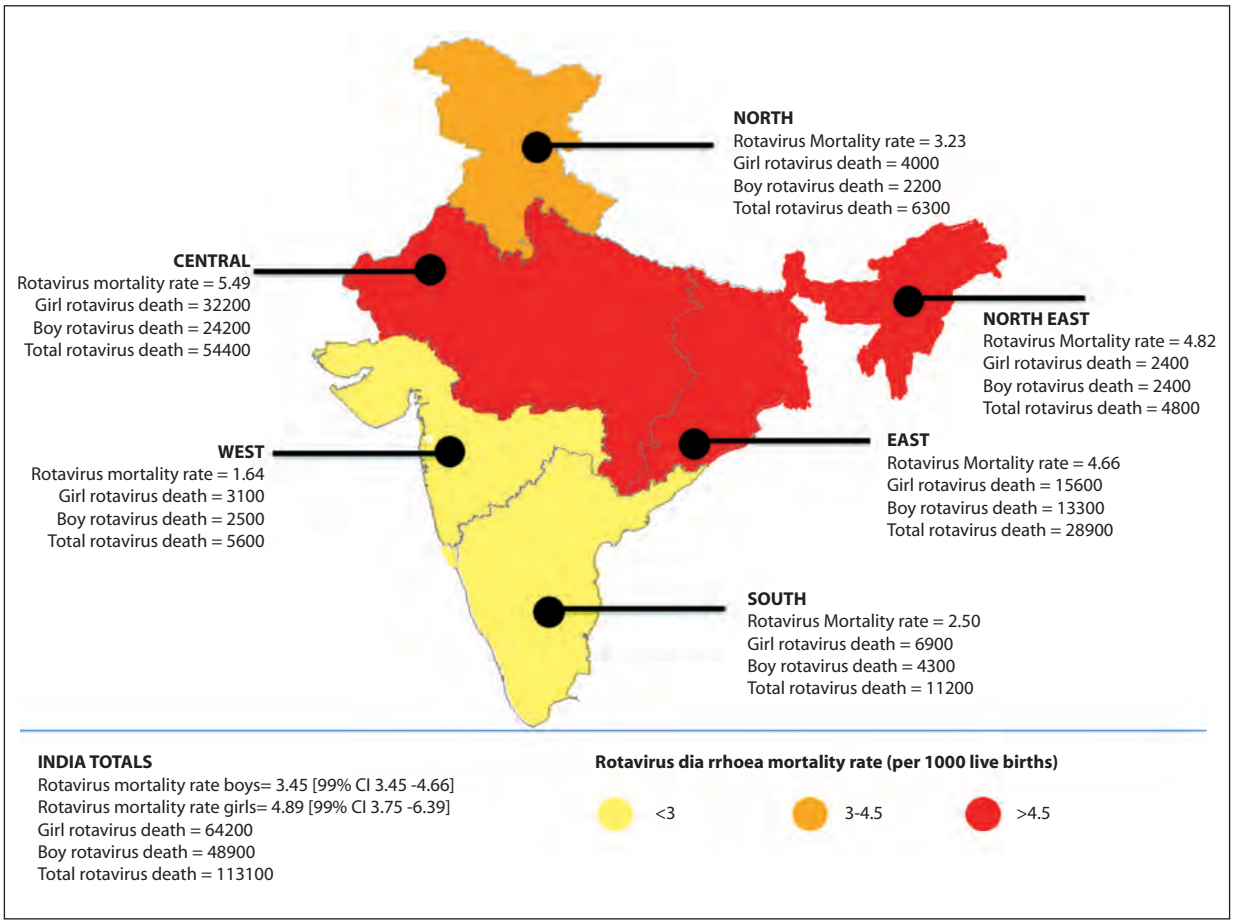
2.5 Modes of transmission

Rotavirus is highly contagious. Individuals suffering rotavirus diarrhea often shed large amounts of virus in the stool. Rotaviruses are spread primarily by the faecal-oral route directly from person-to-person or indirectly via contaminated fomites. During first episode of rotavirus infection, rotaviruses 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 states and 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 among infants <1 year old). 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 among infants <1 year old).

Figure 3: Rotavirus-attributable diarrheal deaths and mortality rates among Indian children younger than 5 years, by age and sex[2]



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. Studies have documented seasonal variation in rotavirus infection, with increased incidence during winter season throughout India.

2.7 Diagnosis of rotavirus infection

Clinically, it is not possible to differentiate rotavirus infection from other infections causing diarrhea 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 confirming, 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-person contact. The only specific intervention strategy is immunization. The rotavirus vaccine along with other interventions for prevention of diarrhea (exclusive breastfeeding for 6 months and continued breastfeeding with appropriate complementary feeding, vitamin A supplementation in children 6-59 months, early case 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 benefit and impact in reducing under five deaths 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 1,22,000-1,53,000 diarrheal deaths 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 is prevention of rotavirus diarrhea by immunization with rotavirus vaccine.

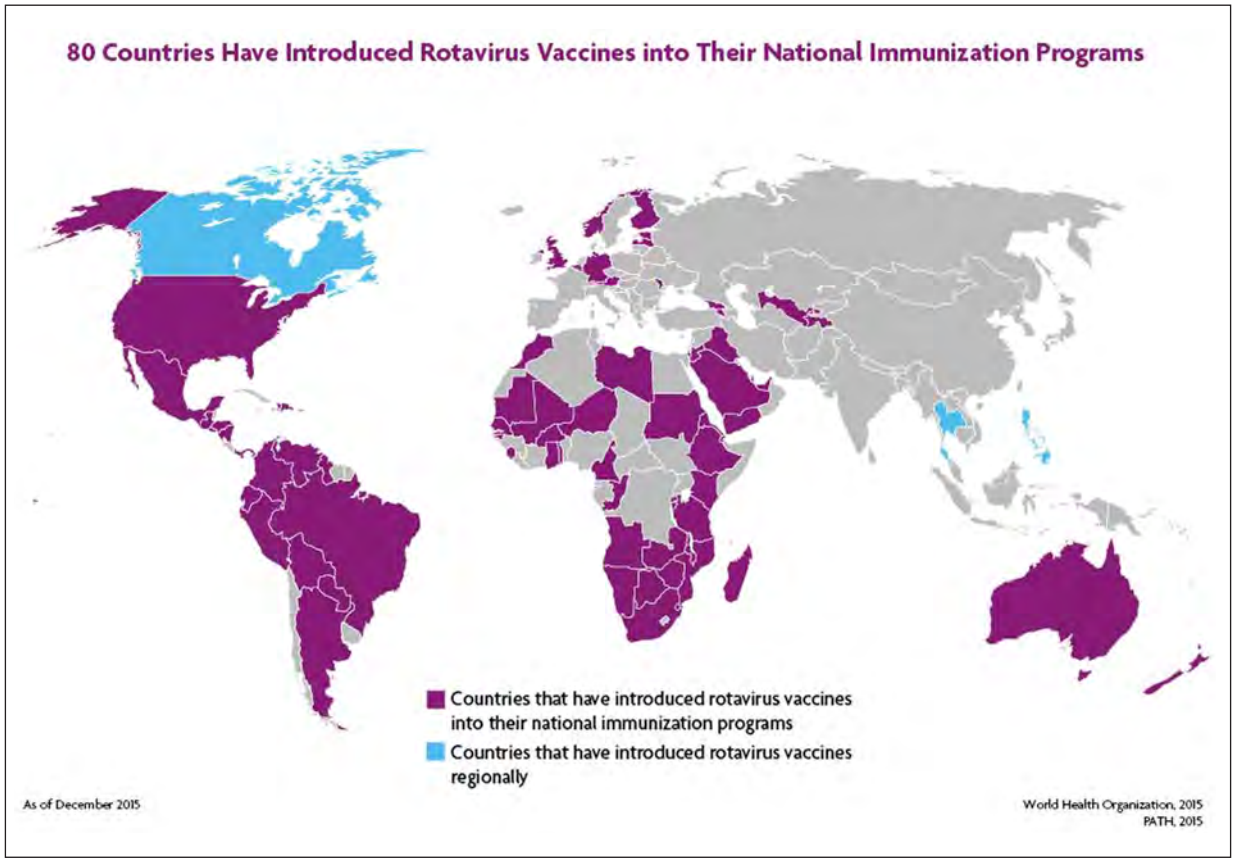
CHAPTER 3

ROTAVIRUS VACCINE GLOBAL SCENARIO

3.1 Recommendations by World Health Organization (WHO)

WHO recommends that Rotavirus Vaccines be introduced into every country's national immunization programme. As of December 2015, 80 countries have introduced Rotavirus vaccine in their national immunization programmes. The rotavirus vaccines are available in more than 100 countries through the private market.

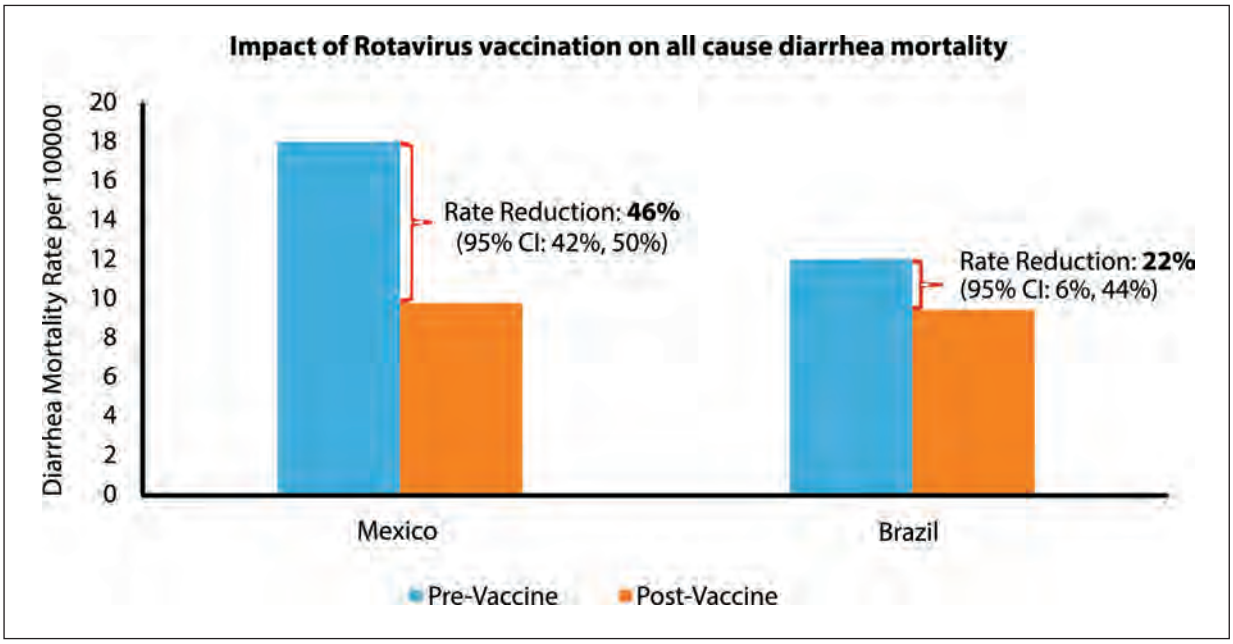
Figure 4: The 80 countries with Rotavirus vaccine in national immunization programmes[3]



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



3.3 Currently Licensed Rotavirus Vaccines

There are three Rotavirus Vaccines available in market;

- Rotavac® (ORV116E), a monovalent vaccine containing suspension of live rotavirus 116E (G9P[11]) prepared in Vero cells manufactured by Bharat Biotech. It is derived from a neonatal strain isolated in India and given in 3 doses at ages 6 weeks, 10 weeks and 14 weeks.
- Rotarix® (RV1), a monovalent Rotavirus Vaccine (contains the RIX4414 rotavirus strain; G1P[8]) manufactured by GlaxoSmithKline Biologicals. It is given in 2 doses at ages 2 months and 4 months.
- RotaTeq® (RV5), a live Attenuated Pentavalent human bovine reassortant Rotavirus 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.

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. Following a multisite clinical trial, Rotavac® was licensed in India by Drug Controller General (India) in 2013 and 2015.

For programmatic reasons, the Government of India recommends rotavirus vaccine upto a maximum of one year of age for BCG, Pentavalent, IPV and Rotavirus.

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 ranges from 40-60%. As per WHO position paper (2013), there is also some evidence that Rotavirus vaccination leads to herd protection in unvaccinated older children and adults.

3.5 Interaction with other vaccines

Rotavirus vaccine may be co-administered with other routine childhood immunizations (i.e Pentavalent and OPV). Based on WHO recommendations, if the routine childhood immunizations are initiated later than 6 weeks of age and/or at intervals of more than 4 weeks the rotavirus vaccine can still be co-administered with other routine vaccines. Breast feeding does not significantly impair the response to rotavirus vaccines.

Key Points

- According to WHO estimates (2008) Rotavirus is responsible for more than 450,000 deaths annually in children less than 5 years of age.
- WHO recommends that rotavirus vaccines be included in national immunization programmes as part of a comprehensive approach to reduce the impact of diarrheal disease.
- 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.
- As of December 2015, 80 countries have included rotavirus vaccines in their national immunization programmes.
- Rotavirus vaccine is given orally and prevents severe diarrhea and hospitalizations due to Rotavirus infection.
- The NTAGI has recommended introduction of Rotavirus vaccine in the national immunization programme of India.
- Rotavirus vaccine will be administered to all infants at 6, 10 and 14 weeks along with OPV, Pentavalent, vaccine for first two doses and along with OPV, Penta IPV vaccines for the third dose.
- The maximum eligible age limit of one year is applicable to BCG, Pentavalent, IPV and Rotavirus vaccine under the UIP in India.
- There are currently three licensed orally administered rotavirus vaccines available in market and in use 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), Ministry of Health and Family Welfare (MoHFW), the Government of India (GoI) has decided to introduce Rotavirus vaccine in the Universal Immunization Programme (UIP) in a phased manner. Like the other UIP vaccines, Rotavirus vaccine will also be supplied by the Government of India free of cost. The current operational guidelines refer to introduction of Rotavirus vaccine in the Universal Immunization Programme (UIP) in India. The rotavirus vaccine will be given to all new birth cohorts as per schedule up to one year of age as was done during Pentavalent and IPV vaccine introduction.

4.2 Presentation

- Rotavirus vaccine is a live attenuated, oral liquid vaccine and is available in 10 dose vial and does not require reconstitution.
- Each dose is of 5 drops (0.5ml). The carton pack for 10 dose vial contains 30 vials or 300 doses.
- The vaccine is in a liquid frozen form. In liquid form, the vaccine is generally pink in colour and may sometimes change to orange or light yellow in colour. This change in colour does not impact the quality of the vaccine.
- The vaccine is supplied with a pink coloured dropper that is longer and wider than the dropper used for OPV. The vaccine should be administered only with the dropper supplied by the manufacturer

Figure 6: Rotavirus vaccine and package

4.3 Storage

The Rotavirus Vaccine should be stored at -20°C at GMSDs, State, Regional and district stores, in the walk-in freezers (WIFs) or deep freezers (DFs). Cold chain points below district level should store vaccine at +2°C to +8°C, in ice-lined refrigerators (ILRs). In the ILR, Rotavirus vaccine should be stored at or above BCG level. (Figure 11). Rotavirus vaccine should be transported in cold boxes with conditioned ice-packs along with other UIP vaccines. Rotavirus vaccine should be transported to session sites along with other vaccine in vaccine carrier with conditioned ice packs.

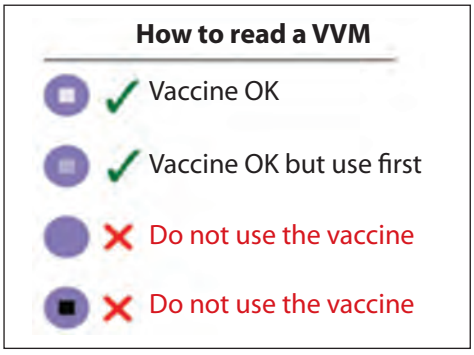
The droppers for administration of the vaccine are to be stored at room temperature as freezing can cause the droppers to crack.The droppers are to be supplied along with the other dry supplies outside the vaccine carrier.

4.4 Storage volume

The cold chain storage volumes occupied by each dose of Rotavirus vaccine supplied in a 10 dose vial is 3 cm^3.

4.5 Vaccine vial monitor

Rotavirus Vaccine vial has Vaccine Vial Monitor-2 (VVM2) dot as part of the label. This is a time -temperature sensitive dot 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 colour or darker than the outer circle, the vial should be discarded.

4.6 Vaccination schedule, dosage and route of administration

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

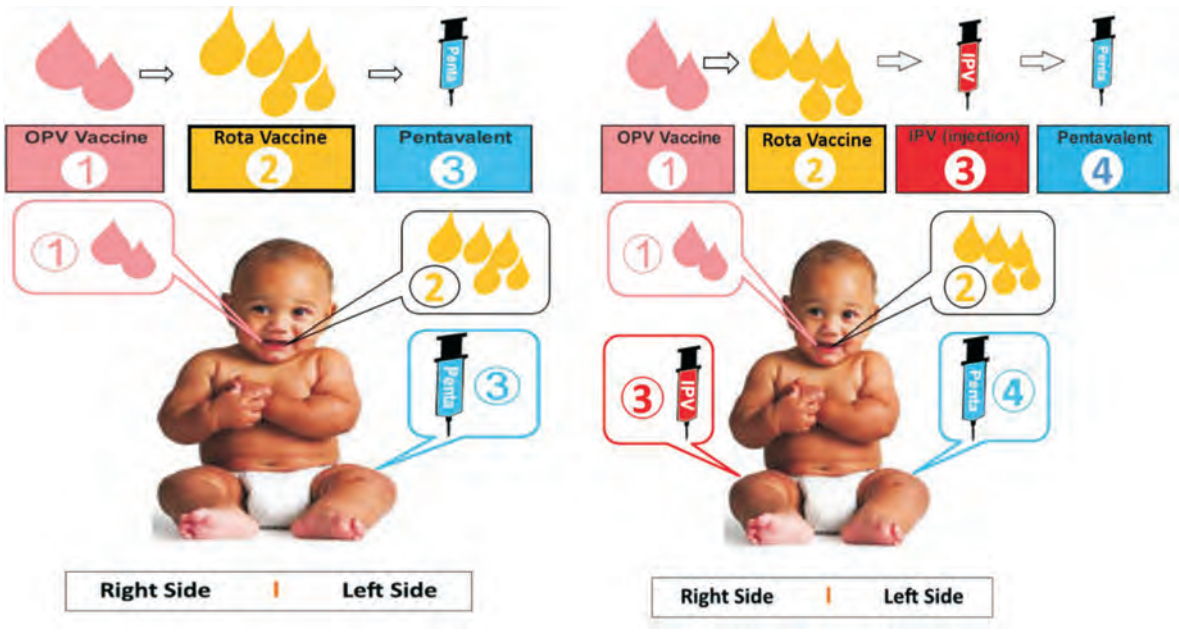
Table 2: Updated schedule including Rotavirus vaccine

Age	Current schedule	After introduction of Rotavirus
At birth	BCG, OPV-0, Hep B birth dose	BCG, OPV-0, Hep B birth dose
6 weeks	OPV-1, Pentavalent-1	OPV-1, Rota-1, Pentavalent-1
10 weeks	OPV-2, Pentavalent-2	OPV-2, Rota-2, Pentavalent-2
14 weeks	OPV-3, Pentavalent-3	OPV-3, Rota-3, IPV, Pentavalent-3
9 months	MCV-1, Vit A*, JE-1#	MCV-1, Vit A*, JE-1#
16-24 months	DPT-B1, OPV-B, MCV-2, JE-2#	DPT-B1, OPV-B, MCV -2, JE-2#
5-6 Years	DPT-B2	DPT-B2
10 years	TT	TT
16 years	TT	TT
**Vitamin A to be given every 6 months till five years of age.* *#JE vaccine given in selected districts.*		
BCG: Bacillus Calmette-Guerin; DPT: diphtheria-pertussis-tetanus; HepB: Hepatitis B; Hib: Haemophilus influenzae type b; JE: Japanese Encephalitis; MCV: Measles containing vaccine- measles alone or MR/MMR; OPV: oral polio vaccine; TT: tetanus toxoid; IPV: inactivated poliovirus vaccine. Rota- Rotavirus vaccine		

Each dose of the Rotavirus vaccine consists of 5 drops. It is to be given orally at 6, 10 and 14 weeks, along with first, second and third doses of OPV and Pentavalent vaccine.

The preferred sequence for administration of vaccines to a child is OPV vaccine (2 drops) - Rotavirus vaccine (5 drops) - Pentavalent vaccine for first and second dose and OPV vaccine (2 drops) - Rotavirus vaccine (5 drops) – IPV - Pentavalent vaccine for third dose. Observe the child for 30 minutes after vaccination (Fig. 7).

Figure 7: The sequence of vaccine administration with Rotavirus vaccine



Sequence of vaccines for 1st and 2nd doses

Sequence of vaccines for 3rd dose

4.7 Steps in administration of Vaccine

Figure 8 below shows steps in administration of vaccine.

- For administration of vaccine keep the vial and dropper ready. Ensure that separate droppers are to be used for each vial. Note that the dropper for Rotavirus vaccine is pink in colour, longer and wider than the OPV dropper and these cannot be interchanged.
- Pull out the aluminum seal along the indicated mark.
- Tear off as shown in steps 3 and 4 of Figure 8 to remove the aluminum seal.
- The vaccine vial with the seal removed has a rubber stopper. Pull out the rubber stopper.
- Connect the dropper firmly to the vial.
- Write the date and time of opening the vial
- Open the dropper cap.
- Position dropper at 45^0 angle. Administer 5 drops into the mouth of the baby. Ensure that the dropper does not touch the mouth of the baby.
- Once opened, the vial is to be used within 4 hours.

Figure 8: Steps in administration of Rotavirus vaccine

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 maximum 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, two more doses of the vaccine should be given with an interval of 4 weeks between two doses to complete the course.

Infants who are coming for their second or third dose of OPV and pentavalent, will complete the schedule with OPV and pentavalent vaccine only. **Rotavirus vaccine is not to be started with second or third dose of OPV and Pentavalent vaccine.**

4.9 Screening of children before administration of Rotavirus vaccine

The infants coming for vaccination must be screened to identify the conditions where Rotavirus vaccine is not to be administered or deferred.

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

- Known or documented allergic reaction to the vaccine.
- 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 and 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

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 vaccine manufacturers

As the composition of the available Rotavirus vaccines and dosage guidelines are different, Rotavirus vaccine from same manufacturer is to be used to complete the immunization schedule of an infant. Rotavirus Vaccines from different manufacturers should not be used for different doses of an infant. If the parents of an infant report incomplete vaccination with other rotavirus vaccine, it is necessary to administer three doses of Rotavirus vaccine in the UIP. If parents are moving to private sector for subsequent doses, it is necessary to use the same vaccine received earlier for completion of the schedule.

4.12 Interaction with other vaccines

Rotavirus vaccine may be co-administered with other routine childhood immunizations (i.e DPT, Pentavalent, Hep B and OPV).

4.13 Long term protection and booster dose

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 opened vaccine vial

A rotavirus vaccine vial can be used upon a maximum of 4 hours after opening and therefore it is mandatory to write date and time of opening vial as applicable for all other vaccines. The open vial policy is not applicable for the Rotavirus vaccine and all partially used vaccine vials should be sent back to cold chain point for management as per guidelines. The partially used vaccine vials returned from the session sites are to be kept separately for at least 48 hours as per the recommended norms under revised open vial policy 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 (Govt. of India, 2015). AEFI causality assessment will inform about the potential association with Rotavirus vaccine.

Remember

- Once opened, use the Rotavirus vaccine vial for a maximum of 4 hours only.
- Date and time of opening a rotavirus vaccine vial must be documented on the vial.
- Return the partially used Rotavirus vaccine vial to the PHC after the session along with the other used vaccine vials.
- The used vaccine vials are to be treated as per guidelines of vaccine related biomedical waste.

Key Points

- Each dose of Rotavirus vaccine is 5 drops.
- Rotavirus vaccine has a VVM 2, which is used for the least 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 to be used within 4 hours of opening.
- Infants coming for the 2nd or 3rd doses of OPV and pentavalent vaccine will NOT be given Rotavirus vaccine.
- During the initial introduction of Rotavirus vaccine, only infants coming for first dose of Pentavalent vaccine and OPV will be given 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, two more doses of the vaccine should be given with an interval of 4 weeks between two doses to complete the course.
- Any AEFI should be reported as per Government of India AEFI surveillance and operational guidelines.

CHAPTER 5

OPERATIONALIZATION OF ROTAVIRUS VACCINE INTRODUCTION FOR UIP

5.1 Preparedness assessment for Rotavirus Vaccine introduction in India

The introduction of Rotavirus 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.

The 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 Rotavirus 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 pentavalent 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 states should review their 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 3 lists the 14 components incorporated in the checklists.

Figure 9: Preparedness Assessment Checklists

Table 3: Components of state & district preparedness assessment checklists

Essential components	
1. Human resources vitals	8. Waste management and injection safety
2. Background information	9. Monitoring and evaluation
3. Microplanning status	10. Adverse Events Following Immunization
4. Training status	11. Mobilization
5. Recording & reporting practices	12. Advocacy and communication
6. Vaccine coverage and wastage	13. Surveillance
7. Vaccine management, transport and logistics	14. Cold chain maintenance
Additional components	
15. General impressions	16. 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 the product of the target population, three dose per child and wastage factor. Every beneficiary will require three doses at 6, 10 and 14 weeks. Considering vaccine wastage rate of 25% (for 10-dose vial) and buffer stock of 25%, the annual vaccine requirement can be calculated as follows:

Annual vaccine requirement = (Number of beneficiaries X Number of doses per infant X wastage factor) + (Number of beneficiaries X Number of doses X wastage factor X 0.25)

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

$$\text{Number of vials needed} = \frac{\text{Number of vaccine doses}}{\text{Number of doses in the vial (10 for 10 doses vial)}}$$

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

5.2.2. Wastage rate and buffer stock

A Rotavirus vaccine vial has to be discarded after 4 hours of opening the vial. It is assumed that two to three doses out of the 10 dose vial will be wasted. Thus for initial period wastage of 25% (wastage multiplication 1.33) has been proposed. Based on the documentation of wastage during initial months, the wastage factor can be revised.

The buffer stock recommended is 25% for the vaccine for the initial years. Based on the data on coverage and vaccine utilization, the buffer stock may be revised and appropriate buffer stocks calculated for the following years. All efforts should be made to minimize vaccine wastage at all levels. **The open vial policy is not recommended for Rotavirus vaccine.** The buffer stock is meant for managing sudden and unexpected shortages. The amount of buffer stock recommended is generally 25% of the annual requirement.

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

Table 4: 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
Measles, JE and Rotavirus vaccine	25% and the wastage multiplication factor for calculation is 1.33
IPV, OPV, Pentavalent Hepatitis B, DPT, TT	10% and the wastage multiplication factor is 1.11. Open vial policy is applicable for vaccines under this category.

5.2.3 Assessing the cold chain space and inventory

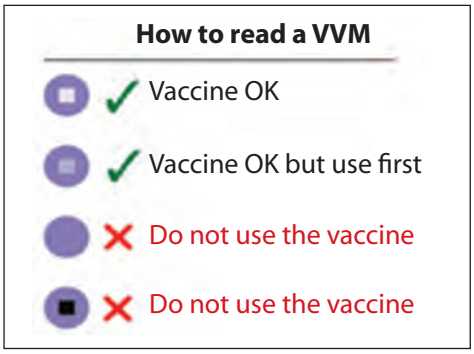
The cold chain infrastructure in India is a wide network of cold chain stores consisting of government medical supply depots (GMSD), state, regional/divisional vaccine stores, and district and PHC/CHC vaccine storage points. The cold chain network in the country has been the backbone to ensure that the right quantity and right quality of vaccine reaches the target population. Cold chain space availability has increased after introduction of Pentavalent vaccine, due to the reduced requirement of DPT and hepatitis B vaccines. The Districts and States must review the cold chain space available 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 requires 3cm^3 (10 dose vials). Therefore assuming 25% wastage rate similar to other UIP vaccine Net Storage Volume required per dose would be 3.9 cm^3. Therefore, 11.97 cm^3 of additional cold chain space would be required per infant at any cold chain point.

(Note – Net Storage Volume = 1.33 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 10: Reading vaccine vial



Rotavirus vaccine is heat sensitive vaccine and loses its potency when exposed to temperatures outside the range recommended by the manufacturer. 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, and changes from light to dark. Before use, check the VVM on each vaccine vial. If inside square is the same colour, or darker than the outer circle (stage 3 or 4), do not use the vaccine. The colour of VVM on Rotavirus vaccine vial changes faster than that on other vaccines.

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 11.

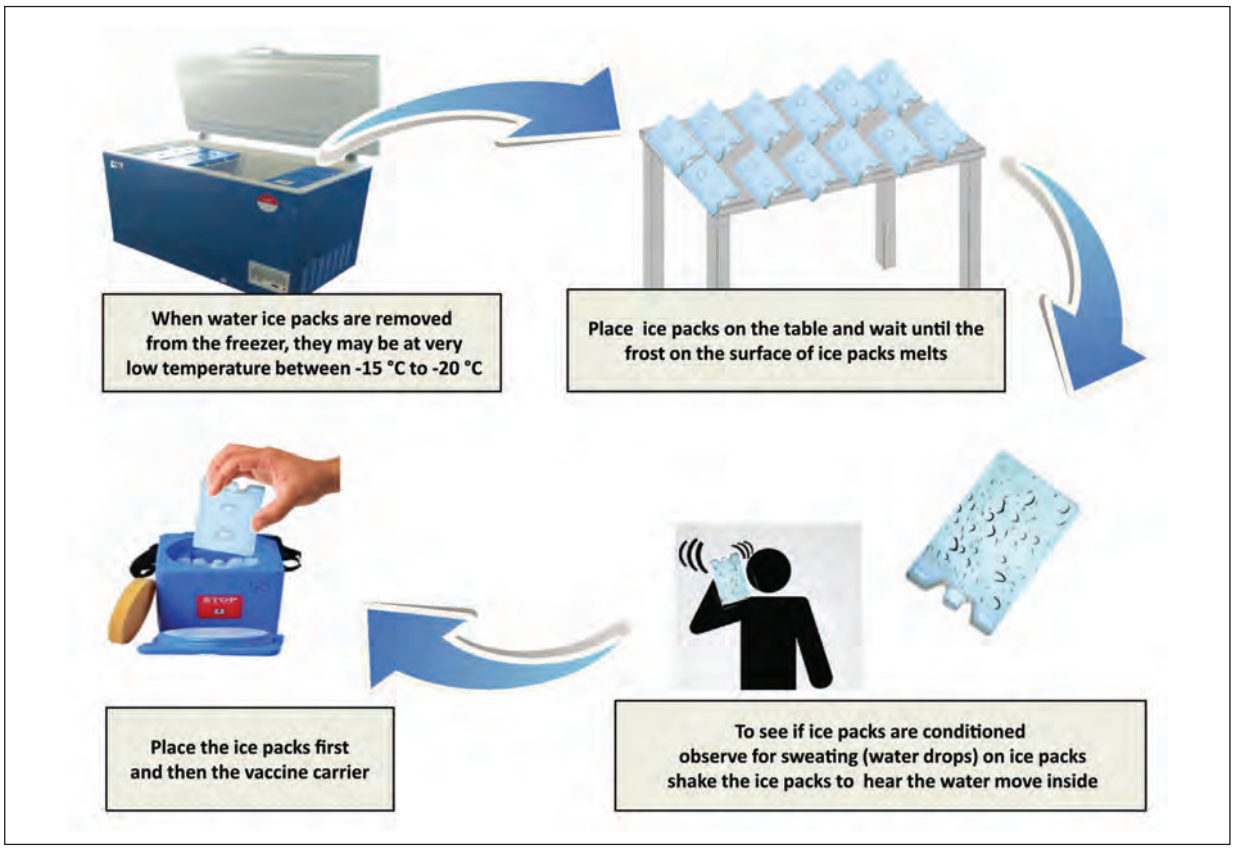
Figure 11: Vaccine/diluents storage in the ILR

5.2.6 Conditioning of water ice packs

In order to ensure correct storage of vaccines and diluents, the following procedure should be followed.

- Ensure that the insulated vaccine carriers are clean before use and at end of the day.
- At start of session day, take all the frozen ice-packs you need from the freezer and close the door.
- Lay 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.
- Dry the packs and line the walls of the insulated vaccine carrier with them.
- Place the vaccines inside a zipper polybag and ensure that the container is properly closed.
- Allowing ice packs to thaw means that the initial freezing temperature is lost, so that the temperature in the insulated carrier does not drop below 0°C.
- Properly conditioned water ice packs constitute the best method to maintain the temperature of the insulated carriers and cold boxes.
- There should be sufficient ice packs to ensure that the vaccines are totally surrounded during transportation.

Figure 12: 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 FEFO (first-expired, first-out). Expiry date should always be checked whenever a vial is opened. Never use vaccines after 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. 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. 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), cold chain handlers, supervisors, data managers and frontline health workers and their supervisors. The ASHAs are also to be oriented for effective community mobilization. The officials and staff of the Department of Women and Child Development such as child development project officers (CDPOs), integrated child development services (ICDS) supervisors and Anganwadi workers also need to be trained at the same time. In addition, plans should be drawn up to orient the faculty of Paediatrics 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 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 cadres of staff involved in routine immunization. Each state where Rotavirus vaccine is to be introduced is expected to conduct State ToT workshops (1.5 Days duration). This excludes Rotavirus vaccine advocacy and launch workshop.

Subsequently, the district level officers will conduct district-level training for block medical officers and Paramedical Supervisors of their district. These Medical Officers and Paramedical Supervisors (including the ANM School Trainers) will, in-turn, be responsible for training health workers, including ANMs, supervisors and cold chain handlers. The MOs and Paramedical Supervisors will also orient the ASHAs and AWWs in their areas.

Table 5: Training plan at different levels for Rotavirus vaccine introduction

Level	Training Workshops	Duration
State	ToT (DIOs, MOs, Dist. IEC Officers)	1+0.5 day
District	Medical Officers	1 day
Block	Health Workers (ANM, LHV, Cold Chain Handlers, Supervisors)	4 hours
	Mobilizers (ASHA, AWW + ANM)	2 hours

Every opportunity should be utilized for sensitization of any new vaccine introduction. For example, state/ district task force meetings and medical officers' trainings are ideal to discuss Rotavirus vaccine introduction topics. The state, district and sub-district programme managers should remember that trainings should exclusively be held as per timelines recommended in this guideline.

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

Table 6: 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
Step 2	Before administration of Rotavirus vaccine, check the age of the beneficiary ◆ Three doses of Rotavirus vaccine are to be given along with the 1, 2, 3 doses of Pentavalent vaccine and OPV ◆ In the case of delayed initiation of initiation of vaccination, Rotavirus vaccine can be given maximum up to 1 year of age. ◆ If the vaccination is delayed beyond 1year of age, Rotavirus vaccine is not to be given
Step 3	Before administration check for any contraindication. Don't give Rotavirus vaccine to infants with 1. Known or documented allergic reaction to the vaccine. 2. History of documented intussusception or abdominal surgery or intestinal malformation. 3. Known case of immunodeficiency.
Step 4	Vaccinate the child with OPV before giving Rotavirus vaccine. Administer 5 drops of the vaccine orally using the dropper supplied with the vaccine. Remember Rotavirus vaccine is a liquid vaccine, so no reconstitution is required. Vaccinate the child with Pentavalent after rotavirus vaccine administration, and IPV and Penta vaccines in case of third dose
Step 5	Record the Rotavirus vaccination dose schedule and date of administration on the immunization card and register
Step 6	Return the unopened and opened Rotavirus vaccine vial after the immunization session as per guidelines

6.2 Reporting and recording of Rotavirus vaccine

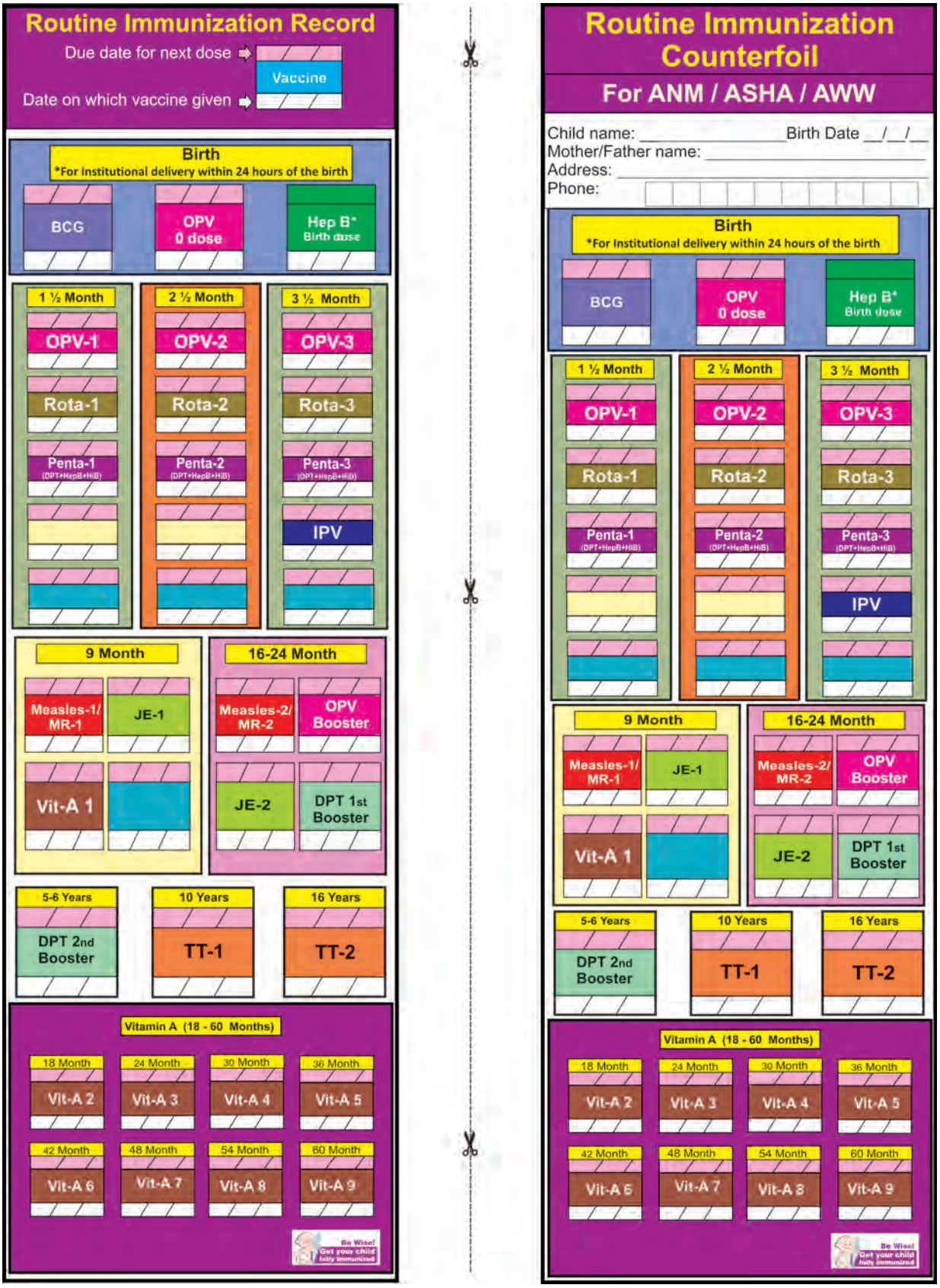
All recording and reporting formats should be revised well in time to include Rotavirus vaccine before the introduction of vaccine. These revised formats should be distributed before introduction and ensure that during health workers' training, an exercise for filling the MCP card should be conducted.

Inclusion of Rotavirus vaccine will be required in vaccine stock forms, immunization cards, due lists, tally sheets, monthly progress reports at all levels, maternal and child health (MCH)/ immunization register, coverage monitoring charts, supervisory checklists, computer databases, immunization coverage surveys and evaluation formats as well as AEFI reporting formats.

The modified MCP card is given below. The reporting of Rotavirus vaccination will be done through existing reporting mechanisms such as the health management information system (HMIS) and the mother and child tracking system (MCTS). MoHFW is in process of updating the HMIS and MCTS portal to include Rotavirus vaccine coverage reporting.

In HMIS, Rotavirus vaccine will find its place under the heading Child Immunization (M6) number of infants from 0 to 11 months subhead. Please do not record Rotavirus vaccine under any other heading.

Figure 13: The Immunization Card



CHAPTER 7

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

The inclusion of Rotavirus Vaccine into the UIP schedule 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 at different levels of storage, logistics and financial needs for each district and sub-district levels, starting from the more peripheral levels and moving towards the higher levels.

The broad steps involved for the introduction of Rotavirus Vaccine are similar to the recently introduced pentavalent and IPV vaccines. 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 10 dose vials.
- Assess cold chain space accordingly.
- Three doses administration of Rotavirus vaccine at 6, 10 and 14 weeks of age along with OPV, Penta and in case of third dose with IPV as well.
- In delayed cases, Rotavirus vaccine schedule can be initiated up to a maximum of 1 year.
- Open vial policy is not applicable for Rotavirus vaccine.
- Vaccine should only be introduced in the districts that have completed the recommended trainings.
- Refrigerator mechanics to visit all vaccine storage points 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 Rotavirus vaccine in the universal immunization programme.

7.1.1 State task force for immunization (STFI)

- STFI should be convened periodically to steer key messages for 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 and the State Health Society (SHS).
- 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, JSI and other key routine immunization partners involved in immunization at state and district levels are expected to proactively support the authorities in providing quality information/monitoring data at STFI and district task force for immunization (DTFI) levels for appropriate actions.

7.1.2 Assess State preparedness

The state needs to assess the preparedness of districts using standardized checklists that have been customized for rotavirus introduction. Quantitative data should be reviewed, compiled and reflected in the state preparedness checklist. In case the State has undertaken preparedness assessment exercise recently for Pentavalent or IPV 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 state oversight team – Mission Director, National Health Mission (NHM) and Director, Family Welfare. The assessment should be completed as per timeline. Following this the state preparedness checklist needs to be forwarded for review at the national level to the Deputy Commissioner, Immunization Division, Nirman Bhawan, New Delhi.

7.1.3 Track preparation in high-priority districts

- Assign state observers to track planning, preparation, launch and implementation of Rotavirus vaccine in the state with a special focus on districts identified under Mission Indradhanush.
- They should visit these districts and provide oversight to activities for introduction of Rotavirus vaccine, including participation in DTFI and assessment of district preparedness using checklists.

7.1.4 Strengthening routine immunization micro-plans

- All high-risk areas (HRAs) identified in polio microplans and all additional sessions planned under mission Indradhanush should be incorporated into the RI microplans. Ensure that all vulnerable sections are provided an equal opportunity to avail services.
- Monitor completeness of all components of microplanning.

7.1.5 Indenting and delivery of vaccine and logistics

- Ensure availability of required doses of Rotavirus vaccine, droppers and other logistics. 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 10 dose vials.
- Assess cold chain space for 10-dose vials and check for any need in augmentation of the cold chain space. The cold chain space deficit needs to be addressed before introduction.
- To ensure smooth launch and inclusion of Rotavirus vaccine in routine immunization programme, all cold chain handlers and frontline health workers should be trained before Rotavirus vaccine introduction.

7.1.6 Training workshops for health workforce at state-level

This is a critical activity and needs timely planning and implementation. Conducting these training of trainers (ToT) workshops 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, JSI and others should proactively support the states and districts in planning, sensitization of health officials and monitoring the quality of training.

The training at different levels including target trainees, trainers and duration is summarized in the Table below.

Table 7: State level ToT (2 day) and Media sensitization workshop (half day)

Sl No.	Trainees	Trainers	Timeline
1a. State ToT day 1	**Medical Officers** *DIO and 2 MOs per district (3 persons per district).* Also include surveillance medical Officers (SMOs) of WHO-NPSP, UNICEF, JSI, state programme manager (NHM), state information education and communication (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), (1-2 officials per organization dealing with cold chain to be invited from agencies such as WHO, UNICEF, UNDP, CORE, CARE, others).	SIO with support from state cold chain Officer, Deputy Commissioner (MoHFW) and partners –WHO NPSP, UNICEF, ITSU, JSI, BMGF and others partners	4th – 6th January 2016 (1 month before launch)
1b. State ToT Day 2	**District IEC Officers (focal persons)** *DIO + 1 District IEC Officer (nodal person) from each district for sensitization at state level.* 1-2 officials per organization dealing with IEC/ media handling to be invited from agencies such as WHO, UNICEF, UNDP, CORE, CARE, others.	SIO with support from WHO, UNICEF, ITSU JSI, BMGF, GHS and other partners, State IEC consultant, media officer, partners	
2.	**Media Sensitization Workshop** *Media personnel (journalists)*	SIO with support from UNICEF, ITSU, JSI, WHO. IAP members, other experts, partners, government officials	17th January to 3rd February 2016 (1 to 3 weeks before launch)

7.1.7 Dissemination of guidelines/revised formats/IEC materials

- Disseminate relevant guidelines and training material during training to each category of health staffs for introduction of pentavalent vaccine
- Ensure printing of IEC materials in local languages in adequate numbers. IEC materials should be clear, attractive and easy to read. They should provide focused messages and contain adequate information about the vaccine.
- Ensure that all the updated reporting and recording tools including immunization component in mother-child protection (MCP) card, registers, due lists, etc. are printed and disseminated in time. Appropriate translation in local languages should be undertaken if required. Ensure use of this updated material in the sensitization workshops at all levels.

7.1.8 Tracking beneficiaries (left-outs and drop-outs)

- Undertake headcount for estimation of beneficiaries by ANMs/ ASHAs/AWWs for improved micro planning and tracking.
- Use standardized tools for microplanning and estimation of beneficiaries. Ensure it is a time-bound activity and gets completed in 1–2 weeks
- State health authorities and partners should intensively monitor this 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.

7.1.9 Intensify monitoring and supervision

- Intensify supervision and monitoring of programme at district, block, session and house-to- house levels through government functionaries and partners.
- Use standardized RI monitoring formats provided by MoHFW.

7.1.10 Communication planning

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

7.2 District-level Rotavirus introduction activities

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

7.2.1 District task force for immunization (DTFI)

- DTFI should be convened periodically to steer all activities for introduction of Rotavirus vaccine in the district, including obtaining commitment and support for introduction of this vaccine 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 and the District Health Society (DHS).
- Districts should make best use of lessons learnt from the polio programme and pentavalent vaccine introduction to strengthen RI. Make best use of this new vaccine introduction opportunity to highlight issues that need attention for corrective action.
- WHO, UNICEF and other key RI partners at district level are expected to proactively extend support in providing quality information/monitoring data to DTFI for guiding and taking appropriate actions.
- Ensure that the district refrigerator technician attend the DTFI meeting.
- Representatives of urban local bodies should be invited in DTFI.

7.2.2 Assess district preparedness

- 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 pentavalent vaccine and IPV 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 district oversight team – District Magistrate and Chief Medical Officer.

7.2.3 Track high-priority blocks

- Senior district health officials have to be identified and deployed to visit and provide oversight to activities for introduction of Rotavirus vaccine in high-priority blocks and urban areas, including participation in DTFI and assessment of district preparedness using checklists.
- In Mission Indradhanush Phase 2 districts, the DTFI should review the existing observer plan and see if the same observers could be deployed as observers for Rotavirus vaccine introduction as well.

7.2.4 Strengthen RI microplans

- All high-risk areas (HRAs) identified in polio microplans and all additional sessions planned under mission Indradhanush should be incorporated into the RI microplans.
- Ensure that all vulnerable sections and high risk groups are provided an equal opportunity to avail services.
- For improved microplanning, ANMs/ ASHAs/AWWs should undertake a head count survey for estimation of beneficiaries by using standardized tools. This has to be a time bound activity (1–2 weeks) and has to be intensively monitored by government functionaries and partners.
- DTFI to monitor the completeness of microplans.

7.2.5 Indenting and delivery of vaccines and logistics

- Ensure availability of required doses of Rotavirus vaccine and other logistics. 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 10-dose vial.
- Assess cold chain space with 10-dose vials.
- Vaccine should only be introduced in the districts that have completed recommended trainings. To ensure smooth launch and merger of Rotavirus vaccine in routine immunization, all cold chain handlers and frontline health workers should be trained before Rotavirus vaccine introduction.
- It is preferred that all vaccine storage (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.
- DHS and DTFI are responsible for providing support to issues requiring attention.

7.2.6 Training workshops for the health workforce at district level

- Prepare a training calendar to train the health workforce.
- 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, UNICEF and others are expected to proactively support the district in planning and sensitization to the workshop activities including 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, lady health visitors (LHVs) and health supervisors) 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 8.

Table 8: Details of District training workshops (1 day)

Sl No.	Trainees	Trainers	Timeline
	Medical officers *Blocks to identify and nominate the names of at least 3 officials (2 MOs + 1 others as nominated by block MO) 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	21st to 26th January 2016 (10-14 days before launch)

7.2.7 Dissemination of guidelines/revised 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 Tracking beneficiaries (left outs and dropouts)

- Undertake headcount for estimation of beneficiaries by ANMs/ ASHAs/AWWs for improved micro planning and tracking.
- Use standardized tools for microplanning and estimation of beneficiaries. Ensure that it is a time-bound activity and gets completed in 1–2 weeks.
- State health authorities and partners should intensively monitor this 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.

7.2.9 Assessment of cold chain capacity and functionality status

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

7.2.10 Intensify monitoring and supervision

- Rotavirus vaccine introduction needs to be monitored and supervised at all levels. Based on GoI guidelines intensify supervision and monitoring of RI at district, block, session and house-to-house 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 mobilization monitoring data will lead to increase in coverage and help reduce dropouts and left outs in the community.

7.2.11 Communication planning

- The district health department in coordination with other department and partner agencies the CMOs and DIO should plan and conduct IEC and social mobilization activities focusing on high risk areas. The Local mobilization activities should include special efforts in reaching the dropouts.
- 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 into UIP:

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 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 (completed in 1–2 weeks) 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 Rotavirus vaccine and other logistics.
- Rotavirus vaccine supply from Government of India will be in 10 dose vials.
- For smooth launch and merging Rotavirus vaccine in routine immunization programme ensure 100 percent training of cold chain handlers and front line health workers before vaccine introduction.
- Rotavirus vaccine is a heat sensitive vaccine. Avoid temperature fluctuation and exposure to high temperature, which may cause wastage of vaccines. Ensure that all vaccine storage (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 visits and share the feedback in DTFI.
- DHS and 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 made to understand the importance of follow up of dropouts and should educate caregivers on the consequences
- WHO, UNICEF, JSI and other partner agencies are expected to support the Rotavirus vaccine introduction activities at district /block level, including monitoring the quality of training.
- Details of training at block level are given in Table 9.

Table 9: Block/Planning Unit-level training workshops

Sl No.	Trainee	Trainers	Duration	Timeline
1.	**Health workers** (ANMs, LHVs, health supervisors, cold chain handlers)	District and block master trainers (DIO, 2 MOs and Paramedical Supervisors/ ANM TC teachers trained at state level + 2 block level MOs trained at district level). They will be supported by other trained officials such as district/block level data handlers and IEC officers , district vaccine and cold chain handlers	4 hours	21st January to 3rd February 2016 (7 to 10 days before launch)
2.	**Mobilizers** (All ASHAs, AWWs, ANMs and mobilizers)	District and block master trainers (DIO, 2 MOs and Paramedical Supervisors/ ANM TC teachers trained at state level + 2 block level MOs trained at district level). They will be supported by other trained officials such as ASHA coordinators, AWW Supervisors at the district level and others	2 hours	

7.3.4 Disseminate the guidelines/ revised formats/ IEC materials

- 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 and gets completed in 1–2 weeks.
- 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.
- Share the due list formats and revised immunization component in the MCP card.
- Demonstrate the use of counterfoil using immunization tracking bag with a focus on "missed dose tracking".

7.3.6 Intensify monitoring and supportive supervision

- Strengthen monitoring and supportive supervision through 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 the 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 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 and UNICEF continues to be of significance in strengthening of health systems and programmes in India. The technical support provided by WHO, UNICEF, ITSU and JSI and other partner agencies such as RMNCHA, BMGF, INCLEN, GHS, ICMR, PATH, UNDP, 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 Rotavirus vaccine in India is a critical step forward in the effort towards reducing infant mortality and under-five mortality. It is therefore very important for all stakeholders – the public and policy makers alike to understand the value of this vaccine in the UIP. A well planned communication strategy has been developed to ensure that launch of Rotavirus vaccine builds upon the past experiences in improvement in vaccine coverage and reduction in IMR and U5MR.

8.1.1 The objectives of the communication plan

- Correct positioning of Rotavirus vaccine introduction into the routine immunization schedule.
- Clear and strategic communication as it may coincide with IPV introduction in some states.
- To strengthen of capacities of health workers in inter personal communication for effective delivery of Rotavirus vaccine and routine immunization.
- Capacity building of HWs for microplanning of communication activities at the community level.
- Generate an enabling environment through an impactful discourse around Rotavirus vaccine and through positive media reporting and involvement of key stakeholders and influencers.

8.1.2 The key components of the communication strategy

- Building 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, polio partners, development partners, nongovernmental organizations (NGOs) and media
  - » Media briefings through specialized Rotavirus vaccine related media kit, which will be provided.
  - » Release of Rotavirus vaccine IEC materials, operational guidelines, etc.
- Advocacy with key stakeholders such as public representatives, government, private medical networks and doctors, religious leaders, media, etc.
- 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
- Capacity development of health workers to create activation plan in the community:
  - » Training of master trainers on Rotavirus vaccine introduction – ToTs at state/district and block levels.
  - » Cascade training of frontline workers on frequently asked questions (FAQs) related to Rotavirus vaccine.
  - » Micro-planning and tracking of children due for Rotavirus vaccine.
  - » Mothers meetings for Rotavirus vaccine introduction.
  - » Influencer meetings and mosque announcements.
- Development of robust IEC and IPC packages on rotavirus vaccine for ensuring visibility for the Rotavirus vaccine introduction through an IEC/IPC package:
  - » Posters for Rotavirus vaccine introduction
  - » Banners/hoardings
  - » Info-kits for Media including factsheets and infographics in simple language.
  - » FAQs for health work force including ANM, ASHA, AWW, social mobilization network, etc.
- AEFI communication strategy and plan

8.2 Launch of Rotavirus vaccine

- A successful launch of Rotavirus vaccine will depend on mass media activities for visibility and awareness as well as capacity building of health workers in interpersonal communication to respond to queries posed by the community. Other related government departments, local media and NGOs should also be briefed and brought on board, so that they may also spread the message and motivate the community to benefit from immunization.
- District and block level officials should receive training in media handling. Sustained engagement with the media is important in dispelling myths and motivating and educating caregivers and communities
- All communication channels should be harnessed – FM radio, television, print and social media – for wide publicity and increased vaccine acceptance among the public.
- A well-publicized launch ceremony should be planned for 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 a new vaccine and periodically thereafter to highlight the benefits of the vaccine and increase awareness.

Steps to be undertaken for the launch events:

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, 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 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 Media briefing

- It is important to ensure that the media is well briefed about the 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:

8.3.1. 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 Rotavirus vaccine facts. 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 beat reporters

8.3.2. 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 on Value of vaccines, disease burden, economic burden on the family etc.
- Organize media briefing with key reporters on 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.

8.3.3. Monitoring and evaluation phase

- Track reporting on 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

A standardized media kit has been developed for the Rotavirus vaccine introduction, which will be provided to the state government for dissemination containing the following:

1. Background note on Rotavirus vaccine introduction
2. Frequently asked questions by media on Rotavirus vaccine (Who, What, When, Where, Why and How)
3. Draft press release
4. Compendium of radio messages for local radio channels on Rotavirus vaccine
5. Format for maintaining media reports on Rotavirus vaccine

8.4 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 10: 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
4	Public representatives Influencers: religious leaders, teachers, self help groups 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

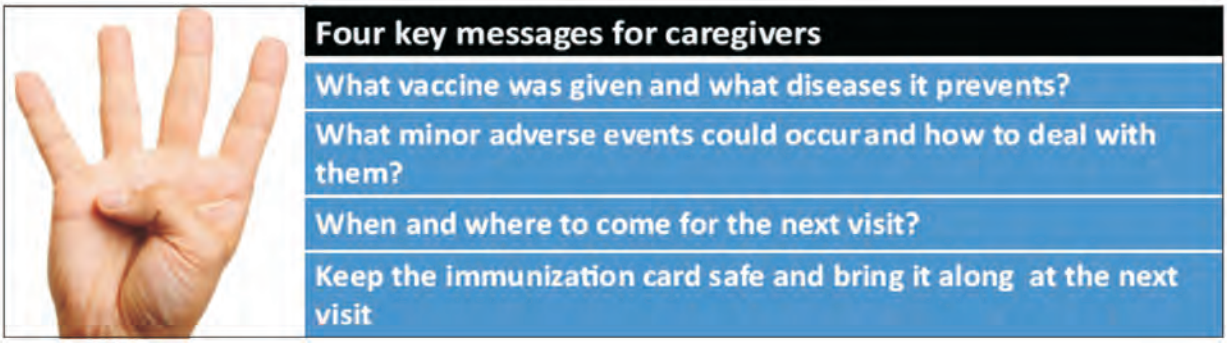
You need to develop your own toolkit using the materials that have been provided in the launch and media toolkits. Make sure that you adapt the Rotavirus vaccine related materials to the audience that you are advocating with so that correct information reaches the audience in the correct format.

8.5 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 14: 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.
3. Service delivery
   - » 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.

- » Encourage use of immunization tracking tools such as tracking bag, MCP card and counterfoils etc.
- » Ensuring delivery of the four key messages 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 launch in India include:

- IEC/IPC package
  - » Booth / Session site Posters for Rotavirus vaccine introduction
  - » Banners / hoardings
  - » Brochure- FAQs for community / mothers / care-givers
  - » Booklet: FAQs for frontline workers (SMNet, ASHAs)
- Training resources
  - » Media kit for training of media personnel
  - » Training curriculum for training of frontline workers

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.

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 have been associated with Rotavirus Vaccines:

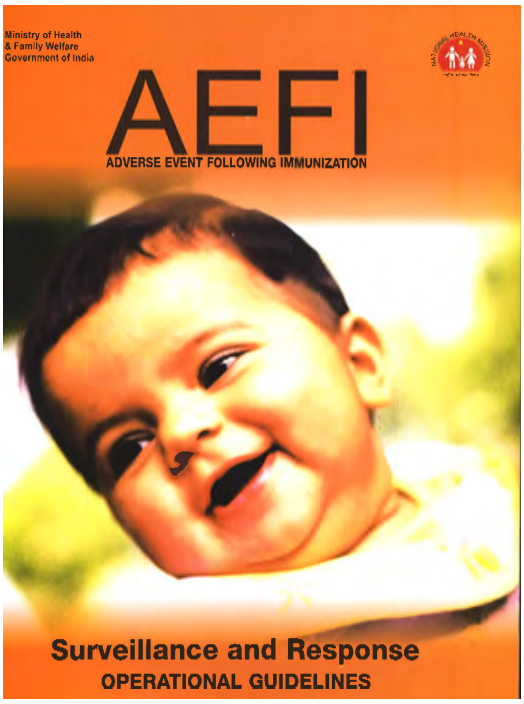
- **Minor transient symptoms:** Rotavirus vaccine may be associated with mild and transient symptoms included vomiting, diarrhea, cough, running nose, fever, irritability and rash. These are to be treated symptomatically. These side effects are classified by the WHO as "minor and common side effects."
- **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 are to be managed with ORS and

Zinc, following the standard management protocol for acute diarrhea.

- **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.
- **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.

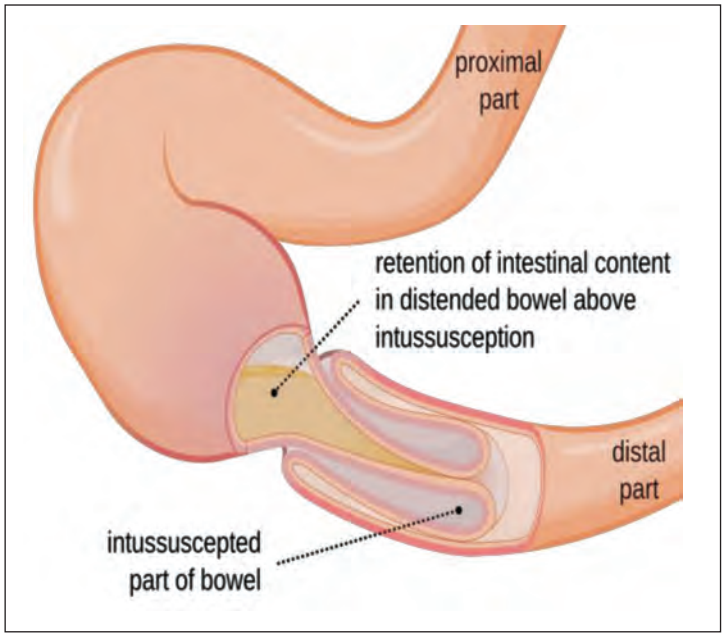
Figure 15: AEFI Standard Operating Procedures



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 per 100000 infants (range 9-328).

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 16: 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

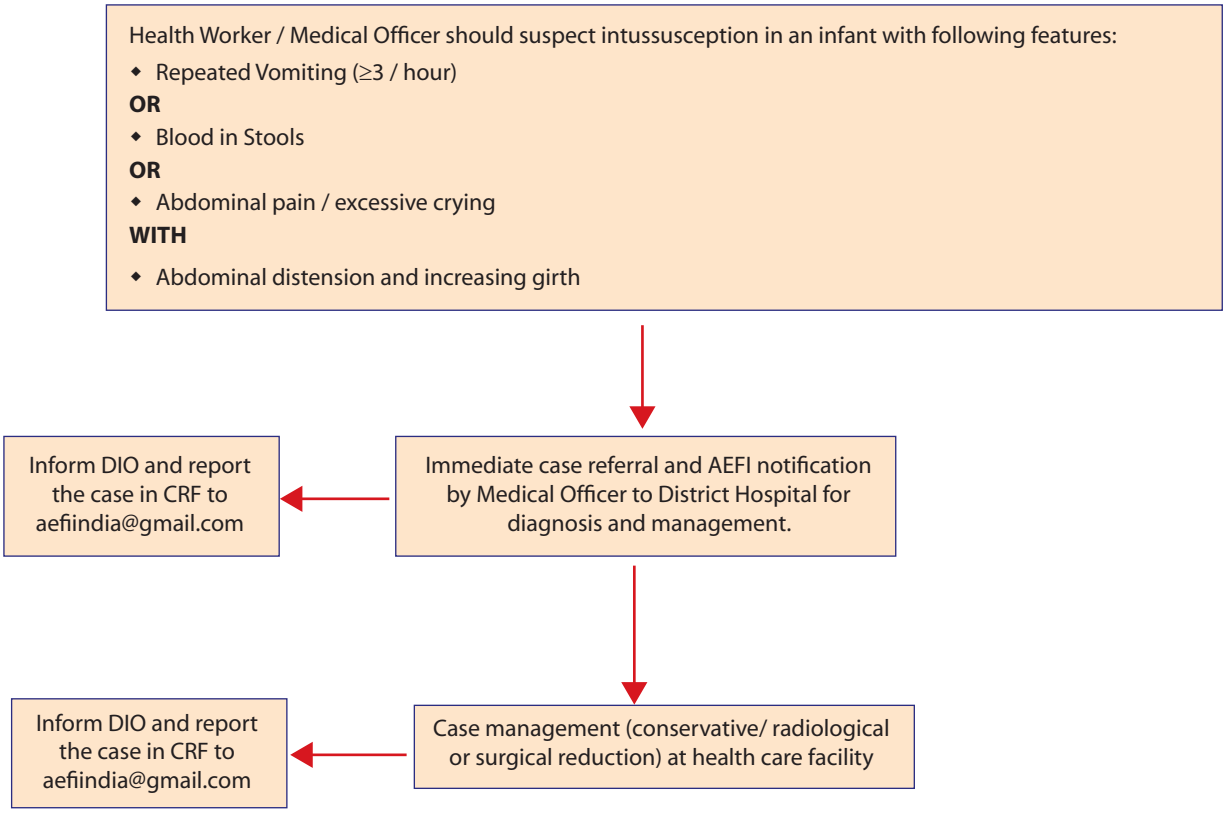
Any infant with clinical features compatible with suspected intussusception must be assessed immediately by the medical officer or pediatrician. Referral should be done immediate, to the designated healthcare facility for management.

9.2 Intussusception Case Management Protocol

Intussusception cases may symptomatic or asymptomatic and may resolve spontaneously. However in case of suspicion, immediate referral should be done to designated healthcare facility for non-surgical or surgical management as decided by the treating doctor.

Before referral, careful assessment for Hypovolemia and dehydration and appropriate Fluid management is critical. Appropriate broad spectrum antibiotics are to be given in presence of 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. Any adverse event should be reported 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 be 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 training of health workers and MOs in detecting, reporting and investigating AEFIs; making available CRFs and other investigation formats with MOs; encourage reporting of serious AEFIs by health workers and medical officers; follow up of investigations for completeness of records within stipulated timelines; etc.
3. Liase 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 hour 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 monitor the functioning of the district AEFI committees in the state; identify silent districts; collaborate with medical college in the state for investigating AEFIs; monitor 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. Liase with pediatricians, surgeons/pediatric surgeons and radiologists in the 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 AEFI 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. 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 is the single designated spokesperson (first respondent) for responding to media queries. In some states, the CMHO/CS or the DM is the spokesperson for the media. In such cases, the immunization manager provides all information to the DM/CMHO regarding the AEFI. Ensure that this spokesperson has been trained in media handling during AEFI. If not organize media-handling skills training in advance
  - » Identify tertiary hospitals in the district (district hospital, medical college, private hospitals within or close to the district with facilities for diagnosing and treating intussusception. Such hospitals should have facilities such as barium Xray, 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 messaging 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 AEFI committee/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.
- 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 AEFI Committee (on the top), and 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 manifold higher than small increase in cases of intussusception that may occur and can be managed in health facilities.

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) at the national level for further action. It is recommended that introduction activities should start 3–6 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 bringing 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 (assigned for high-priority districts) 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 and local administrative officers should be invited by block MOs to observe 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, injection practices of ANMs, injection safety and waste disposal, record keeping and inter-personal communication of service providers.

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.
- The existing mechanisms such as the task force for immunization, other interactions and review meetings should be used for feedback and information sharing for appropriate corrective measures and follow-up.

10.3 Monitoring supply of vaccines and logistics

- Available records must be examined for supply, utilization and balance of vaccines, AD syringes (Penta and IPV vaccines) and droppers (Rotavirus vaccine and OPV) and verified physically to see whether there is a logical association between vaccines, AD syringes and droppers supplied and used.

- If the following are found, there is a need to explore and address the reasons:
  - » The utilization of the vaccine, AD syringes and droppers shows a pattern of rapid increase or decrease week after week;
  - » Doses consumed for vaccines that are provided at the same time (OPV/Pentavalent/Rota vaccines) differ widely from each other for the same period.
- If there is any mismatch between the reported number of doses, AD syringes and droppers used, the vaccinators, doctors, store in-charge and supervising authorities concerned must be consulted to determine the reason for the variation or mismatch.
  - » If their reply is found convincing and realistic, no action is required other than appreciating them.
  - » If the reply points towards problems or irregularities in work/management, solutions need to be discussed with the persons concerned.
  - » The senior authorities should be informed well in time.

10.4 Monitoring the cold chain

- Rotavirus vaccine should be stored below district level between +20C and +80C. It is damaged by exposure to higher temperatures. Therefore, strict attention to ILR temperature and icepacks to be given 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 suspected AEFI thought to be associated with Rotavirus vaccine should be reported in the prescribed GoI format, including hospitalizations, deaths and any other severe or unusual medical event or event clusters.
- If an AEFI occurs, measures should be taken to check the compliance with safety strategies from the existing supervisory checklists and explanations sought for deviations from safety norms such as recapping, non-use of hub cutters and other incorrect practices.

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