



# Introduction of **Rotavirus Vaccine** in the Universal **Immunization** Programme in India

## Frequently Asked Questions

For Medical Officers



**Immunization Division**  
Ministry of Health & Family Welfare  
Government of India

**DECEMBER 2015**



**Be Wise!**  
**Get your child  
fully immunized**



# Frequently Asked Questions

## on

# Rotavirus Vaccine Introduction

## For Medical Officer



### 1. What is Rotavirus?



Rotavirus is a highly contagious virus. It is the most common organism that causes diarrhea among children which may lead to hospitalization and death.



### 2. What are the clinical features of Rotavirus diarrhea?



The clinical features of rotavirus diarrhea may vary from transient loose stools to severe diarrhea with vomiting that may result in dehydration, electrolyte imbalance, shock and death if not treated adequately.

It has an incubation period 1-3 days. It presents usually with sudden onset of watery stools, often accompanied by fever and vomiting. Sometimes pain abdomen may be there. The diarrhea and associated symptoms may last for 3-7 days.



### 3. Is Rotavirus diarrhea serious?



Rotavirus diarrhea is responsible for 40% of children requiring hospitalization due to diarrhea in India. It is responsible for nearly 20 lakh outpatient visits, more than 4.5 lakh hospitalizations and 1.2 lakh deaths annually in India.



### 4. Which children are at risk of getting the Rotavirus diarrhea?



The risk of rotavirus infection continues to persist in all settings. The proportion of diarrhea caused by rotavirus does not vary widely between developed and developing countries.

Approximately 50% of rotavirus-associated deaths occur in the first year of life and about 75% occur in the first two years of life.

In children with undernutrition, diarrhea may be serious with high chance of dehydration and death if not treated adequately.



### 5. What are the modes of transmission of the Rotavirus?



Rotavirus is highly contagious. As per WHO position paper (2013), "Rotavirus transmission occurs primarily by the faecal-oral route directly from person to person, or indirectly via contaminated fomites" and "the virus can live for hours on hands and even longer on hard surfaces."

**Q 6. In which season Rotavirus diarrhea occur most?**

**A** Rotavirus infection and diarrhea can occur throughout the year. Studies have documented increased diarrhea during winter season.

**Q 7. How is Rotavirus diarrhea diagnosed?**

**A** Rotavirus diarrhea cannot be distinguished from diarrhea due to other causes, from clinical features alone. Diagnosis of Rotavirus diarrhea is possible by detecting Rotavirus in stool using laboratory test such as 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.

**Q 8. What is the treatment of Rotavirus diarrhea?**

**A** There is no specific therapy to treat rotavirus diarrhea. The treatment of Rotavirus diarrhea is similar to other acute diarrheas. The rotavirus diarrhea is treated with ORS for fluid replacement and zinc for 14 days. Severe dehydration may require hospitalization for treatment with intravenous (IV) fluids.

**Q 9. Once a child has had Rotavirus diarrhea, can she/he get it again?**

**A** Yes. The child can get repeated infection with Rotavirus. The repeated infections may be milder in nature.

**Q 10. How can Rotavirus diarrhea be prevented?**

**A** Vaccination with Rotavirus Vaccine is the specific preventive option against Rotavirus. Rotavirus vaccine is effective in reducing the hospitalizations and deaths due to diarrhea in children.

General measures to prevent diarrhea like good hygiene, frequent hand washing, safe water and safe food consumption, exclusive breastfeeding and vitamin A supplementation reduce the risk of Rotavirus infection, but are not enough to control the spread of the disease.

**Q 11. How effective is the Rotavirus vaccine?**

**A** The available Rotavirus Vaccines are observed to be effective in preventing severe rotavirus diarrhea by 54-60%. The protective effect of Rotavirus vaccine lasts through 2<sup>nd</sup> year of life.

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





**12. Is Rotavirus vaccine being used in any other country in the world?**



Rotavirus vaccine is being used in national immunization program of 80 countries. Rotavirus vaccine has been in use by private practitioners in India for several years.



**13. Will vaccination with Rotavirus vaccine prevent all diarrheas?**



No. Please remember that the diarrhea is caused by many organisms. Rotavirus vaccine is effective in preventing diarrhea due to Rotavirus only, which is one of the leading causes of diarrhea in children. So the child may still get diarrhea due to other germs and causes even after receiving Rotavirus vaccine.

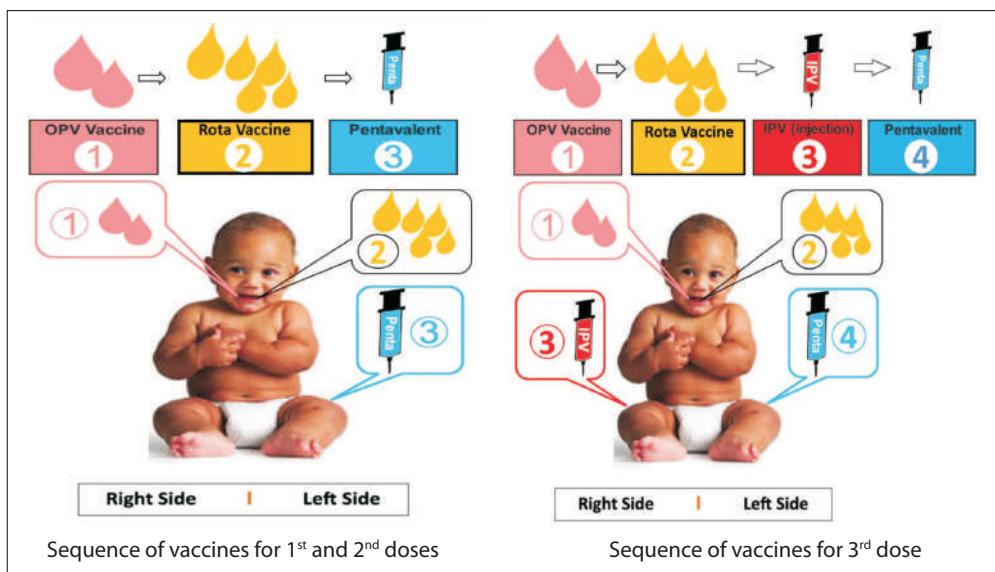


**14. How and when is the Rotavirus vaccine given?**



Rotavirus vaccine is an oral vaccine. The dose of Rotavirus vaccine varies from manufacturer to manufacturer.

The dose of Rotavirus vaccine currently being supplied under UIP is 5 drops given orally. Rotavirus vaccine will be administered to all infants at 6, 10 and 14 weeks along with other vaccines in routine immunization schedule as per the sequence given in the figure below.



**15. Is a booster dose required for Rotavirus vaccine?**



No booster dose of Rotavirus vaccine is recommended. Only three doses at 6, 10 and 14 weeks are required to complete the schedule of vaccination for a child.



**16. Does the breastfeeding need to be withheld for some time before or after vaccination?**



The child can be given breastfeeding before or after vaccination.

**Q 17. What are the clinical contraindications for Rotavirus vaccination?**

- A** The clinical 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.

**Q 18. If the child has minor illness, can the Rotavirus vaccine be given?**

**A** If the child is having minor illnesses like mild fever, upper respiratory infection etc. Rotavirus vaccine can be given. There's no reason to postpone the appointment unless an infant is seriously ill with fever or diarrhea and vomiting. If the infant is well enough to have the other routine vaccinations, then Rotavirus vaccine can also be given.

**Q 19. Is it safe to given multiple vaccinations to a child in one visit?**

**A** Yes. It is safe to give multiple vaccinations to a child in one visit as per national immunization schedule.

**Q 20. What is the appearance of Rotavirus vaccine?**

**A** The Rotavirus vaccine is generally pink in colour and may sometimes change to orange or light yellow. This change in colour does not impact the quality of the vaccine.

**Q 21. What are the similarities and differences between Rotavirus and oral polio vaccine?**

**A**

S No.	Feature	Oral Rotavirus Vaccine	Oral Polio Vaccine
<b>Similarities</b>			
1.	Colour of vaccine	Generally pink in colour, may change to orange or light yellow.	Light pink or yellowish orange.
2.	Mode of administration	Oral	Oral
<b>Differences</b>			
3.	Colour of dropper	Pink	Transparent
4.	Taste	Sweet	Bland to Bitter
5.	Dose	5 drops	2 drops
6.	Schedule	6, 10 & 14 weeks of age	Birth dose for institutional deliveries; Primary doses at 6, 10 & 14 weeks; Booster dose at 16-24 months of age.

**Q 22. What is the maximum age limit for giving the first dose of Rotavirus vaccine?**

**A** The upper age limit for giving the first dose of Rotavirus vaccine is one year of age. Even if the child has received first dose of Rotavirus vaccine by 12 months of age, two more doses of the vaccine should be given at an interval of 4 weeks between two doses to complete the course.

**Q 23. Should Rotavirus vaccine be given to children who have already received first dose of OPV and Pentavalent vaccine?**

**A** No. During the initial period of Rotavirus vaccine introduction, only the infants coming for the first dose of OPV and pentavalent vaccine will be administered Rotavirus vaccine. These children will be given 2<sup>nd</sup> and 3<sup>rd</sup> doses in subsequent visits as per the schedule.

Infants who are coming for their second or third dose of OPV and pentavalent vaccine, 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.

**Q 24. What if a child misses the first dose of Rotavirus vaccine or comes late for first dose vaccination?**

**A** If the child comes after 6 weeks of age for first dose of recommended UIP vaccines, the first dose of Rotavirus vaccine can be given along with first doses of OPV and Pentavalent vaccine upto one year of age.

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.

**Q 25. Will Rotavirus vaccine be given in Mission Indradhanush?**

**A** Yes, Rotavirus vaccine will be given in Mission Indradhanush and follow the same guidelines as for Routine Immunization.

**Q 26. Should Rotavirus vaccine be given to child coming from a state which has not yet introduced Rotavirus vaccine in its schedule?**

**A** Yes, Rotavirus vaccine should be given to a child irrespective to the state she/he comes from, as per the current guidelines.

**Q 27. What if a child misses the second or third dose of Rotavirus vaccine or comes late for vaccination?**

**A** The child can be given the pending Rotavirus vaccine doses at an interval of at least 4 weeks between two doses.

**Q 28. What should be done if a child has received one or two doses of Rotavirus vaccine in private facility?**

**A** Please remember that there are three Rotavirus vaccines available in the market. These vaccines differ in composition and dosage schedule. The vaccination schedule must be completed using the same vaccine. Please follow the steps mentioned below:

*Verify the brand name of the Rotavirus vaccine given on the immunization card. If not written, ask the parents to check with the private Doctor about the name of the Rotavirus vaccine.*

1. *If Rotavirus vaccine given in private facility is same as that being given under UIP, then the next doses can be given from govt. facility under UIP at interval of 4 weeks between doses*
2. *If Rotavirus vaccine given in private facility is NOT the same as that being given under UIP, then the child should be given a new course of all 3 doses of Rotavirus vaccine under UIP, at interval of 4 weeks between doses.*
3. *If the parents are not sure about the name of Rotavirus vaccine given in private facility, start a new course with all three doses of Rotavirus vaccine at an interval of 4 weeks.*

**Q 29. What is to be done if the child is given Rotavirus vaccine first before OPV?**

**A** No problem. If the child is given Rotavirus vaccine first, give the OPV after that.

**Q 30. Is the schedule for prematurely born babies different for Rotavirus vaccine?**

**A** No. The doses of Rotavirus vaccine are to be administered as per the age calculated from date of birth irrespective of the age of gestation when the child was born.

**Q 31. Which government health facilities will provide Rotavirus vaccine?**

**A** Rotavirus vaccine will be provided free of cost through routine immunization sessions under UIP. The vaccine will be provided in all government health facilities including hospitals, medical colleges, urban dispensaries, PHCs, CHCs, subcenters and outreach session sites. It will not be given in a house-to-house campaign mode.

**Q 32. What should be done if Rotavirus vaccine is not available at immunization session?**

**A** The child should be given all available vaccines for which she/he is eligible. Rotavirus vaccine should be given to the child in the next immunization session.





**33. Is there any side effect of the Rotavirus vaccine?**



The Rotavirus vaccine is a safe vaccine. However, mild and transient symptoms included vomiting, diarrhea, cough, runny nose, fever, irritability and rash may be associated with rotavirus vaccination. A rare adverse event known as intussusception (one part of bowel folding/ telescoping into another) has been reported after Rotavirus vaccine. As per the WHO position paper (2013), "in some but not all settings, post-marketing surveillance of both currently available rotavirus vaccines has detected a small increased risk of intussusception (about 1–2/100 000 infants vaccinated) shortly after the first dose."

Such children present with severe pain abdomen (excessive crying) and repeated episodes of vomiting, blood in stool and dehydration. Such children need to be referred immediately to hospital for appropriate management. Also, in such cases, inform DIO and report this AEFI case in CRF to aefiindia@gmail.com. It is important to know that Intussusception also occurs in children without rotavirus vaccine. The rotavirus vaccine offers tremendous benefits by protecting infants and children from rotavirus disease. The risk of adverse events after rotavirus vaccination is much lower than the risk of severe rotavirus disease in unvaccinated children. Hence, rotavirus vaccine is strongly recommended to prevent rotavirus disease in infants and young children.



**34. How many doses of Rotavirus vaccine will be there in one vial?**



Rotavirus vaccine will be supplied in 10- dose vial presentation. The health worker must check for the vaccine details before using the vaccine vial.



**35. Will the Rotavirus vaccine vials have vaccine vial monitor (VVM) on their label?**



Yes. Rotavirus vaccine vials will have a vaccine vial monitor (VVM) on their labels. If the VVM reaches the discard point then do not use the vaccine. As long as the colour of inner square is lighter than the colour of the outer ring, the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour than the ring, the vial should be discarded.

How to read a VVM	
	✓ Vaccine OK
	✓ Vaccine OK but use first
	✗ Do not use the vaccine
	✗ Do not use the vaccine



**36. At what temperature does the Rotavirus vaccine is to be stored?**



The Rotavirus Vaccine should be stored at -20°C at 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.

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 (syringes) outside the vaccine carrier.



**37. How should Rotavirus vaccine be transported between different cold chain points?**



Rotavirus vaccine should be transported in cold boxes with conditioned ice-packs along with other UIP vaccines.



**38. How should Rotavirus vaccine be transported to session sites?**



Rotavirus vaccine should be transported to session sites along with other vaccine in vaccine carrier with conditioned ice packs. The droppers are NOT to be kept inside the vaccine carrier and sent separately outside along with the syringes.



**39. Does Open Vial Policy apply to Rotavirus vaccine?**



The open vial policy is NOT applicable to Rotavirus vaccine like JE, Measles and BCG vaccines. A rotavirus vaccine vial can be used upto 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.



**40. What is the maximum time till when an opened Rotavirus vaccine vial can be used?**



The Rotavirus vaccine vial once opened can be used up to maximum of 4 hours. After 4 hours from the time of opening, Rotavirus vaccine vials should be returned to the cold chain points and kept separately for at least 48 hours as per the recommended norms under revised open vial policy. Then it should be treated as per biomedical waste management protocol.



**41. What If the child spits out the Rotavirus vaccine or vomits immediately after having it?**



Repeat the dose. In case, an incomplete dose is administered (the baby spits up or regurgitates most of the vaccine), repeat the dose to the child in the same vaccination visit. To prevent spitting, please put the drops towards the inner cheek. Avoid putting the drops over the tongue.



**42. What should you do if you find a frozen Rotavirus vaccine vial?**



You can use the vial after it liquefies. Rotavirus vaccine is stored at  $-20^{\circ}\text{C}$  at district level and above and  $2-8^{\circ}\text{C}$  below the district level. The vaccine needs to be liquefied before it is used.



**43. Where should the Rotavirus vaccine be kept at the immunization site?**



Please place the opened Rotavirus vaccine on the ice pack kept outside during the session. As per RI guidelines, the health worker is expected to take out one ice pack at the session site and use the same after opening the heat sensitive vaccine. On Ice Pack- BCG and Measles (place them in the holes on ice pack), OPV, JE and Rotavirus vaccine should be placed on the surface of the ice pack. Remember – IPV, Hepatitis-B, TT, DPT and Pentavalent vaccines should never be kept on the ice pack.





*Developed by*  
**Immunization Technical Support Unit (ITSU) and JSI/India**  
for Ministry of Health & Family Welfare, Government of India