Ministry of Health
& Family Welfare
Government of India

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

Introduction of Rotavirus Vaccine in the Universal Immunization Programme

Frequently Asked Questions

For Medical Officers

Immunization Division
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Frequently Asked Questions on Rotavirus Vaccine Introduction

For Medical Officers

Q **1. What is Rotavirus?**

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

Q **2. What are the clinical features of Rotavirus diarrhea?**

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

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

Q **3. Is Rotavirus diarrhea serious?**

A Rotavirus accounts for 40% of hospitalizations due to diarrhea amongst children in India. It is responsible for nearly 32.7 lakh outpatient visits, 8.72 lakh hospitalizations and 78000 deaths annually in India of which 59,000 occur in the first two years of life.[1]

[1] *John J, Sarkar R, Muliyil J, Bhandari N, Bhan MK, Kang G. Rotavirus gastroenteritis in India, 2011-2013: Revised estimates for disease burden and potential impact of vaccines. Vaccine 2014;32 Suppl.1: A5-9*

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.

There is a high risk of dehydration and death due to diarrhea in undernourished children, if not treated adequately.

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

Rotavirus is a highly contagious virus. As per WHO position paper (2013), "Rotavirus transmission occurs primarily by the faeco-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."

6. In which season does Rotavirus diarrhea occur most?

Rotavirus infection and diarrhea can occur throughout the year, most commonly seen in winter season.

7. How is Rotavirus diarrhea diagnosed?

Rotavirus diarrhea cannot be clinically distinguished from diarrhea due to other causes. Rotavirus diarrhea can be diagnosed in stool specimen, using laboratory tests 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 confirmation, serotyping and further differentiation.

8. What is the treatment of Rotavirus diarrhea?

There is no specific treatment for Rotavirus diarrhea. The treatment of Rotavirus diarrhea is similar to other acute diarrheas, using ORS for correcting fluid and electrolyte imbalance and zinc for 14 days. Severe dehydration may require hospitalization for treatment with intravenous (IV) fluids.

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

Yes, the child can get repeated infections with Rotavirus. The subsequent infections may be milder in nature.

10. How can Rotavirus diarrhea be prevented?

Rotavirus vaccine is the only specific prevention against Rotavirus diarrhea. The 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.

11. How effective is the Rotavirus vaccine?

Available evidences suggest that Rotavirus vaccines are most effective at preventing the most severe and life-threatening cases of Rotavirus diarrhea. The efficacy of Rotavirus vaccines against severe Rotavirus diarrhea in India ranges from 40-60%.[2]

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

[2] *P S Kulkarni et al. A randomized Phase III clinical trial to assess the efficacy of a bovine-human reassortant pentavalent Rotavirus vaccine in Indian infants. Vaccine 35 (2017) 6228–6237*

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

A Rotavirus vaccine is being used in national immunization program of 96 countries. Rotavirus vaccine has been in use by private practitioners in India for several years.

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

A No. Please remember that 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 hospitalizations and deaths due to diarrhea in children. The child may still get diarrhea due to other germs and causes, even after receiving the vaccine.

Q 14. What will be the presentation of the Rotavirus vaccine?

A Rotavirus vaccine is an oral, freeze dried vaccine and supplied in a two dose vial (one dose of 2.5ml) presentation which will be in bundles of one vaccine vial along with one diluent (citrate bicarbonate) vial, two 6 ml oral syringes and one adapter. For every beneficiary one 6 ml oral syringe will be supplied. Oral 6 ml syringes and adapter will be supplied in separate packs.

The adapter will facilitate the withdrawal of diluent for reconstitution and also withdrawal of the vaccine after reconstitution. Out of the two 6 ml oral syringes, one syringe will be utilized for reconstitution and administration of first dose, whereas the second syringe will be utilized for administration of second dose to the subsequent eligible beneficiary. The syringes are strictly for oral use.

Q 15. How will the vaccine be reconstituted and administered?

A Remember, this Rotavirus vaccine is a freeze dried vaccine, so it has to be reconstituted with the diluent supplied along with the vaccine. The entire amount of diluent in the vial should be used to reconstitute the two dose vial of Rotavirus vaccine. The adapter and one 6ml oral syringe will be used for the withdrawal of diluent for reconstitution. The same adapter along with the same 6 ml oral syringe will then be used for withdrawal and administration of 1st dose (2.5 ml) of the reconstituted vaccine. The second

6 ml oral syringe with the help of the same adapter will be used for withdrawal and administration of the 2nd dose (2.5 ml). The syringes are strictly for oral use.

The vaccine should be administered slowly with the nozzle of the 6 ml oral syringe pointed towards the inner cheek (buccal cavity) of the infant.

Q 16. How and when is the Rotavirus vaccine given?

A

The Rotavirus vaccine (RV5), is a live attenuated oral freeze-dried vaccine containing five strains of the virus.

The dose of this Rotavirus vaccine currently being supplied under UIP is 2.5 ml 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 preferred sequence given below:

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

** Wherever applicable*

Sequence of administration of vaccines

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

Q 17. Is a booster dose required for Rotavirus vaccine?

A

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

Q 18. Does breastfeeding need to be withheld for some time before or after vaccination?

A The infant can be breastfed before or after vaccination.

Q 19. What are the clinical contraindications for Rotavirus vaccination?

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

a. Known or documented allergic reaction to the vaccine
b. History of documented intussusception or abdominal surgery or intestinal malformation
c. Known case of immunodeficiency.

Q 20. If the infant has minor illness, can the Rotavirus vaccine be given?

A If the infant has minor illnesses like mild fever, upper respiratory infection etc., Rotavirus vaccine can be given. If the infant is well enough to have the other routine vaccinations, then Rotavirus vaccine can also be given. There's no reason to postpone the vaccination unless the infant is seriously ill, having high grade fever, severe diarrhea or vomiting.

Q 21. Is it safe to give multiple vaccinations to a child in one visit?

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

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. If the child has received first dose of Rotavirus vaccine by one year of age, subsequent 2nd and 3rd dose of the vaccine should be given at an interval of 4 weeks between two doses to complete the course.

23. Should Rotavirus vaccine be started in 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 started with Rotavirus vaccine. These children will be given 2nd and 3rd doses during subsequent visits as per the UIP schedule.

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. The upper age limit for starting Rotavirus vaccination is one year of age.

25. Will Rotavirus vaccine be given in Intensified Mission Indradhanush?

A

Yes, Rotavirus vaccine will be given in Intensified Mission Indradhanush following the same guidelines as for Routine Immunization.

26. Should Rotavirus vaccine be given to a 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 coming from a state which is yet to introduce RVV, as per the current guidelines.

27. What if a child who has received first dose of RVV and has missed second or third dose of Rotavirus vaccine?

A

The child can be given due doses of Rotavirus vaccine (2nd and 3rd dose) at a minimum interval of 4 weeks between two doses.

Q 28. Should the oral freeze dried Rotavirus vaccine be given to a child who has received one or two doses of a liquid Rotavirus vaccine available under UIP in another state?

A

If a child starts the schedule with the liquid Rotavirus vaccine then the child should preferably complete the schedule using the same liquid vaccine. However, in case of inter-state migration, vaccination should not be deferred or denied because the Rotavirus vaccine used for the previous dose (s) is unknown or is different from the Rotavirus vaccine available in the state where the child's family has migrated. The RVV schedule will be completed using the Rotavirus vaccine available in that state under the UIP.

29. 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 four Rotavirus vaccine products available in the market. If a child starts the schedule with the Rotavirus vaccine product "A" then the child should preferably complete the schedule using the same Rotavirus vaccine product 'A'. However, vaccination should not be deferred or denied because the Rotavirus vaccine product used for the previous dose (s) is unknown or is different from the Rotavirus vaccine product available under UIP in that state. The subsequent doses will be administered using the Rotavirus vaccine available under UIP in that state to complete the RVV schedule.

30. 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 OPV after that.

31. Is the Rotavirus vaccine schedule for prematurely born babies different?

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.

32. 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, sub centers and outreach session sites. It cannot be given in house-to-house visits.

33. What should be done if Rotavirus vaccine is not available at immunization session site?

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.

34. What should be done if RVV is not available at immunization session site but is available at the last CCP?

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.

35. Is there any side effect of the Rotavirus vaccine?

A

Rotavirus vaccine is a safe vaccine. However, mild and transient symptoms including 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 as per guidelines.

It is important to know that Intussusception also occurs in children without administration of 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.

Q 36. How many doses of Rotavirus vaccine will be there in one vial?

A

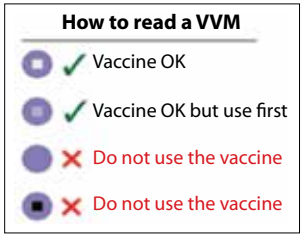
Freeze dried Rotavirus vaccine has to be supplied BUNDLED with the diluent, adapter and oral syringe in a 1+1+1+2 (or its multiples) concept at every level of the supply chain.

There should be a segregated and prominently labelled dry space area at every cold chain point for storing the adapters and oral syringes supplied with the vaccine. For supplying to the session sites too, the vaccine, diluent, adapter and oral syringes are to be bundled. One adapter is for reconstitution of one vaccine vial only and it cannot be reused.

Q 37. Will the Rotavirus vaccine vials have vaccine vial monitor (VVM)?

A

Yes. Rotavirus vaccine vials will have a vaccine vial monitor (VVM). If the VVM reaches the discard point, do not use the vaccine.

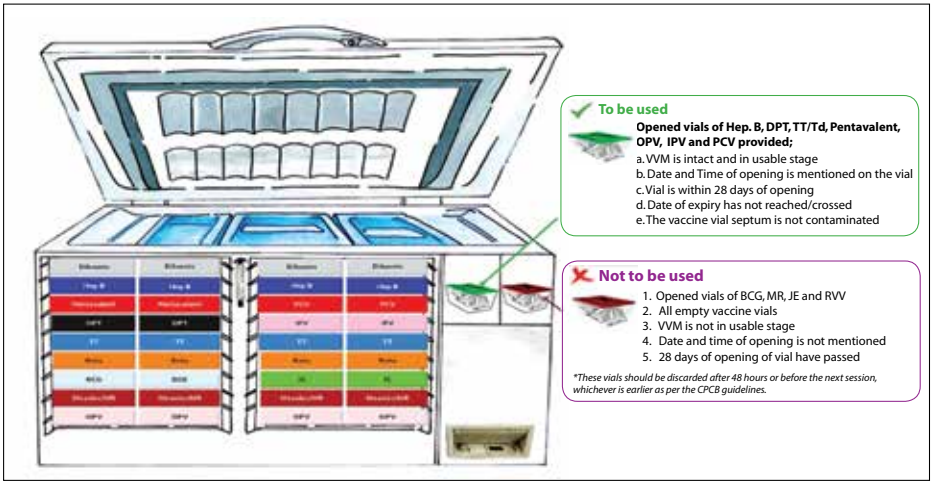


As long as the color of inner square is lighter than the colour of the outer ring, the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour than the ring, the vial should be discarded.

Q 38. At what temperature should the Rotavirus vaccine be stored?

A Rotavirus vaccine should be stored between +2^{0}C and +8^{0}C at all levels. At the last cold chain point from where vaccines are supplied to the session sites, diluent vials should always be kept between +2^{0}C and +8^{0}C in ILR. However, in case of shortage of cold chain space, diluents must be stored in the ILR between +2^{0}C and +8^{0}C at least 24 hours prior to the immunization session.

6 ml oral syringe and adapter used for administration of the vaccine are to be stored at room temperature along with other syringes and OPV dropper. They are to be supplied to the immunization session sites along with the other dry supplies outside the vaccine carrier.



Q 39. How should Rotavirus vaccine be transported between different cold chain points?

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

Q 40. How should Rotavirus vaccine be transported to session sites?

A Rotavirus vaccine, along with its diluent, should be transported to session sites along with other vaccines in a vaccine carrier with four conditioned

ice packs. The 6 ml oral syringes and adapter are not to be kept inside the vaccine carrier, and should be sent separately along with the other dry supplies.

Q 41. Does Open Vial Policy apply to Rotavirus vaccine?

A The open vial policy is NOT applicable to Rotavirus vaccine, similar to JE, MR and BCG vaccines.

A Rotavirus vaccine vial can be used up to a maximum of 4 hours after reconstitution. It is mandatory to write the date and time of reconstitution on the vaccine vial. All partially used vaccine vials should be sent back to cold chain point for disposal as per biomedical waste management guidelines.

Q 42. What is the maximum time till when a reconstituted Rotavirus vaccine vial can be used?

A The Rotavirus vaccine vial once reconstituted can be used up to maximum of **4 hours**.

Q 43. What If the child spits out the Rotavirus vaccine or vomits immediately after having it?

A Repeat the dose (2.5ml). In case an incomplete dose is administered (the infant spits out or regurgitates most of the vaccine), repeat the dose in the same vaccination visit. To prevent spitting, please position the tip (nozzle) of the 6ml oral syringe towards the inner cheek (buccal cavity). Administer the vaccine slowly. Avoid administering the vaccine over the tongue. It should also be ensured that the tip of the syringe (nozzle) is not touched with finger before administration.

44. Where should the Rotavirus vaccine vial be kept at the immunization site?

Please place the reconstituted Rotavirus vaccine vial 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 for placing vaccines that are not freeze sensitive. On Ice Pack- BCG and MR (place them in the wells on ice pack), OPV, JE and Rotavirus vaccine should be placed on the surface of the ice pack. Remember – vials of freeze sensitive vaccines including IPV, TT/Td, DPT, Pentavalent and PCV vaccines should never be kept on the ice pack.

Steps in administration of Rotavirus vaccine

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

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

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

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

- Fix the syringe on the adapter.
- Push the air inside the diluent vial.

- Withdraw entire amount of diluent into the syringe.

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

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

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

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

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

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

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

Notes