



Rotavirus Epidemiology in the Post-Vaccine Era: Insights from Multi-Centric Surveillance from India (2019–2023)



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Background

- Rotavirus is a significant cause of severe diarrheal illness in children aged under 5 years, accounting for approximately 30% of all diarrheal deaths in this age group worldwide.
- In 2017, India was responsible for 16% of global rotaviral deaths among children under 5 years.
- The National Rotavirus Surveillance Network's sentinel platform (2012-2016) found that the burden of rotaviral disease was 36.3% among >25,000 enrolled children under 5 years in India.
- Among the children who tested positive for rotavirus, 64.2% experienced severe- to very-severe diarrhea.
- In India, rotavirus vaccination began in March 2016 with the introduction of the monovalent Rotavac[®] (116E) vaccine, followed by the pentavalent ROTASIIL[®] (G1, G2, G3, G4, and G9) vaccine in April 2018.
- Other WHO pre-qualified global brands available in the private sector include RotaTeq[®] (Merck) and Rotarix[®] (GlaxoSmithKline).

Objective

To assess the burden of acute rotavirus gastroenteritis in children aged under five years following the introduction of an indigenous oral pentavalent rotavirus vaccine ROTASIL[®] into the Universal Immunization Programme in India from 2019 – 2023.

Ethical approvals were obtained from each enrolling site and also from the review board of Christian Medical College, Vellore.

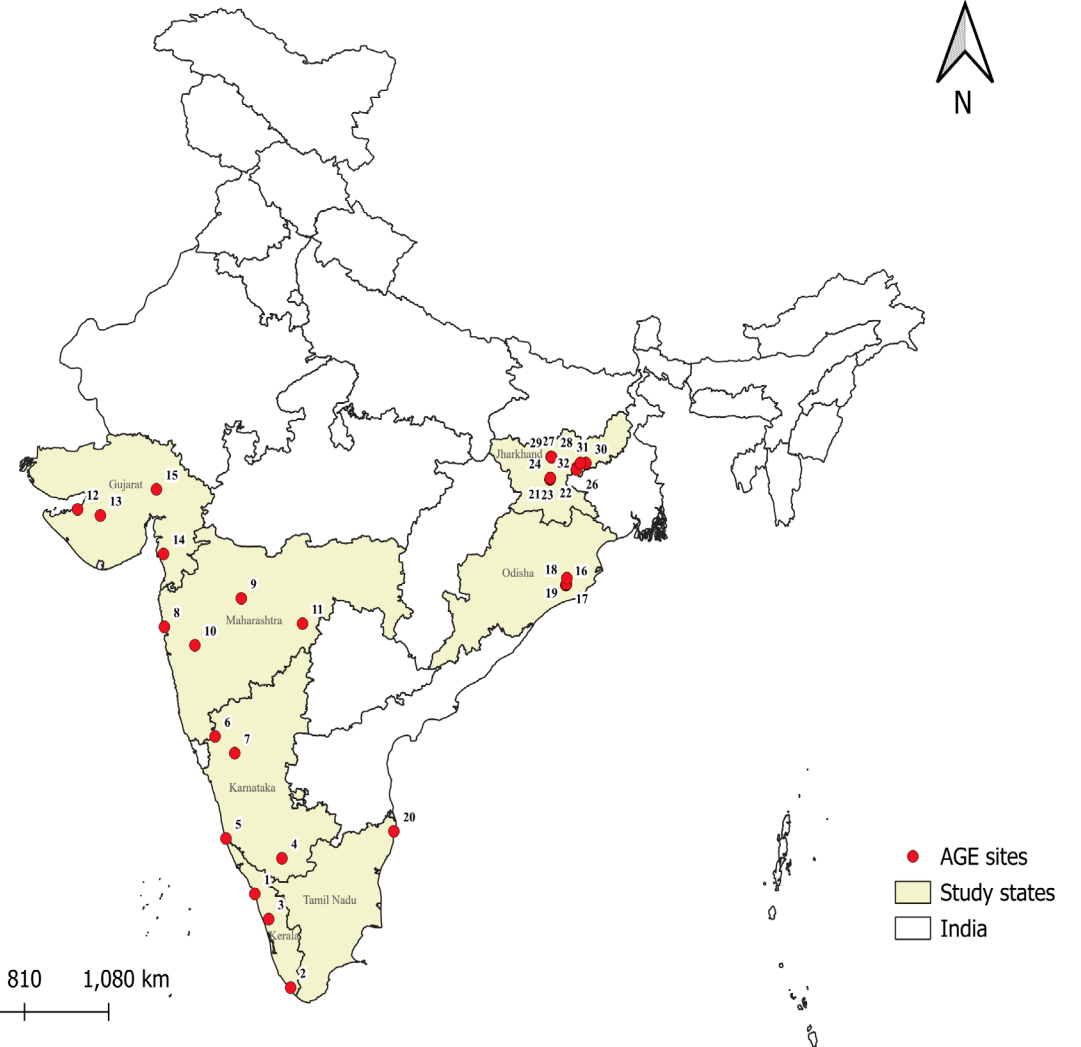
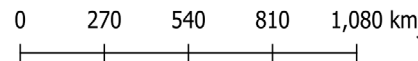
Acute gastroenteritis (AGE) was defined as the passage of three or more episodes of loose stools characterized by a consistency looser than normal within a 24-hour period.

Study states and sites

ROTASIIL[®] introduction in state
Universal Immunization Programme

- Jharkhand – first state – April 7, 2018
- Gujarat – July 1, 2019
- Maharashtra – July 20, 2019
- Karnataka – August 26, 2019
- Kerala – September 6, 2019
- Odisha & Tamil Nadu - switched from Rotavac in all districts - January, 2021

32 sites from 7 Indian states



Methods

Trained staff at all study hospitals screened participants for eligibility:

1. Age (<60 months),
2. Parental consent available,
3. Minimum of 3 episodes of loose stools per day,
4. Duration of loose stools (≤ 7 days),
5. Residence in states with ROTASIIL[®] in UIP,
6. Absence of blood in stools,
7. Not admitted in another hospital for <24 hours

Case Report Forms for all enrolled children filled till discharge, stool sample and vaccination card copies collected, real-time data synced with CMC server

Stool samples transported at regular intervals to WTRL, Vellore, incomplete vaccination history and missing data reconfirmed after review by data management team

Data Analysis

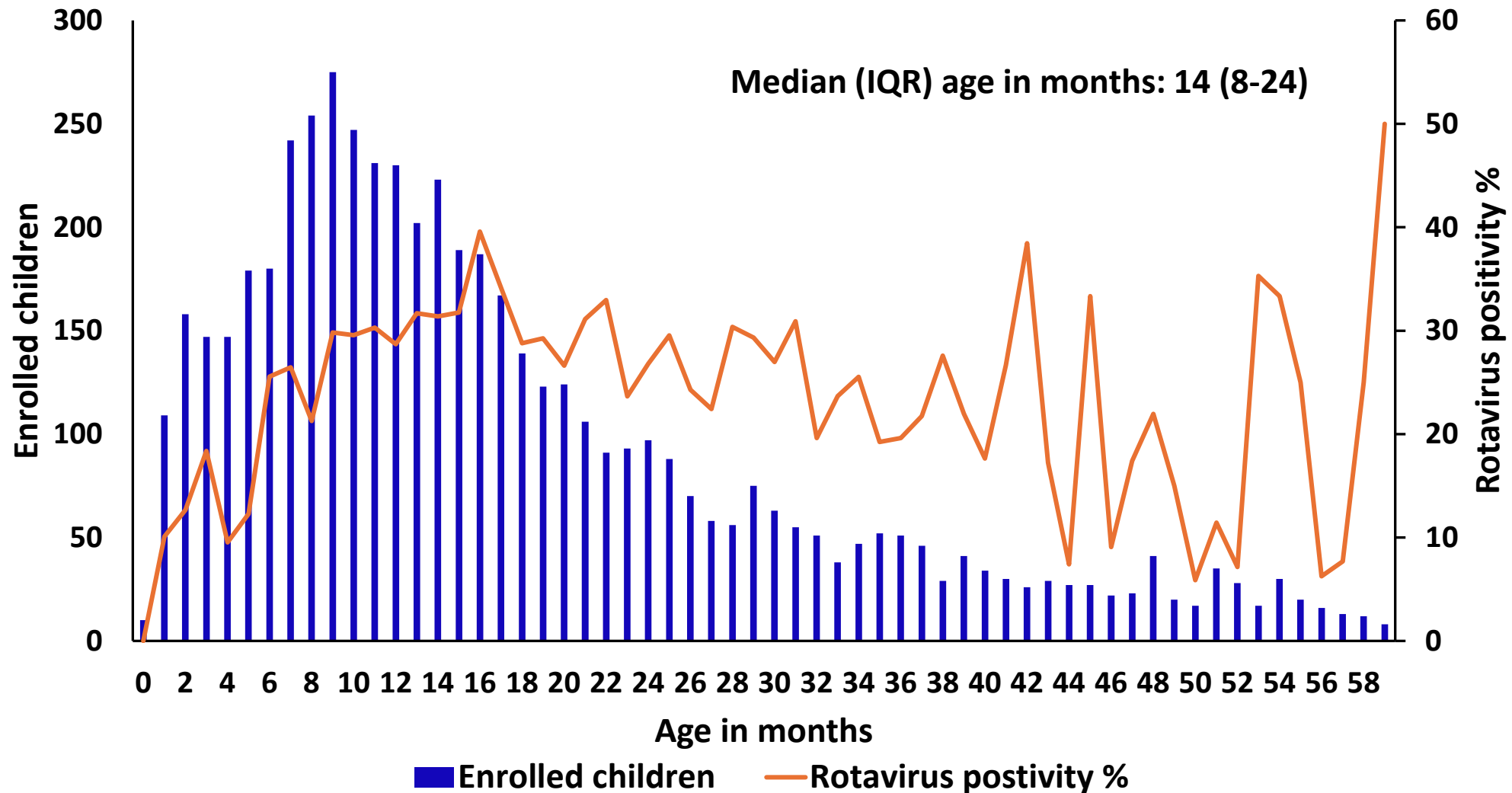
Overview of data collected – regional trends

State & region	Number of <5 AGE screened n (%)	Enrolled children n (%)	Vaccination information available n (%)	Stool samples tested n (%)	Rotavirus positive n (%)
Jharkhand	3,094	1,937	1,799	1,787	711 (39.8)
Odisha	486	365	334	288	67 (23.3)
<i>Eastern region</i>	<i>3,580</i>	<i>2,302 (64.3)</i>	<i>2,133 (92.7)</i>	<i>2,075 (90.1)</i>	<i>778 (37.5)</i>
Maharashtra	679	571	487	529	173 (32.7)
Gujarat	1,618	1,220	1,169	1,149	206 (17.9)
<i>Western region</i>	<i>2,297</i>	<i>1,791 (78)</i>	<i>1,656 (92.5)</i>	<i>1,678 (93.7)</i>	<i>379 (22.6)</i>
Kerala	1,142	666	647	643	115 (17.9)
Karnataka	513	433	381	405	97 (23.9)
Tamil Nadu	348	253	238	195	27 (13.8)
<i>Southern region</i>	<i>2,003</i>	<i>1,352 (67.5)</i>	<i>1,266 (93.6)</i>	<i>1,243 (91.9)</i>	<i>239 (19.2)</i>
Total	7,880	5,445 (69.1)	5,055 (92.8)	4,996 (91.7)	1,396 (27.9)

Overview of data collected – yearly trends

Year of admission	Number of enrolling sites	Number of <5 AGE screened	Children enrolled n (%)	Stool samples collected n (%)	Stool samples tested n (%)	Rotavirus positive n (%)
2019	9	290	189	175	174	34 (19.5)
2020	15	724	545	513	511	260 (50.9)
2021	21	2,147	1,581	1,510	1,494	488 (32.7)
2022	16	1,200	811	757	754	196 (26)
2023	19	3,519	2,319	2,085	2,063	418 (20.3)
Total		7,880	5,445 (69.1)	5,040 (92.6)	4,996 (99.1)	1,396 (27.9)

Age distribution & RV positivity among enrolled children (N=5,445)



Clinical factors & RV positivity (N=4,996)

	Rotavirus positive, n=1,396 (%)	Rotavirus negative, n=3,600 (%)	OR (95% CI)	p
Duration of diarrhea				
Up to 4 days	1,351 (96.8)	3,385 (94)	Ref.	<0.001
5-7 days	45 (3.2)	215 (6)	0.52 (0.37-0.72)	
Maximum number of diarrhea episodes in 24-hour period				
3-5	281 (20.1)	1,033 (28.7)	Ref.	<0.001
>5	1,115 (79.9)	2,567 (71.3)	1.59 (1.37-1.85)	
Vomiting				
Absent	1,198 (85.8)	2,477 (68.8)	Ref.	<0.001
Present	198 (14.2)	1,123 (31.2)	2.74 (2.32-3.23)	
Duration of vomiting (n=4,031)				
Up to 2 days	931 (77.7)	1,764 (71.2)	Ref	<0.001
≥ 3 days	267 (22.3)	713 (28.8)	0.70 (0.60-0.83)	

Clinical factors & RV positivity (N=4,996)

	Rotavirus positive, n=1,396 (%)	Rotavirus negative, n=3,600 (%)	OR (95% CI)	p
Dehydration				
None	405 (29)	1,419 (39.4)	Ref.	
Some (5%)	918 (65.8)	1,974 (54.8)	1.62 (1.42-1.86)	<0.001
Severe (>5%)	73 (5.2)	207 (5.8)	1.23 (0.92-1.64)	0.151
Treated with intravenous fluids				
Yes	1,319 (94.5)	3,040 (84.4)	3.15 (2.46-4.03)	<0.001
No	77 (5.5)	560 (15.6)	Ref.	
Length of hospital stay				
Up to 2 days	701 (50.2)	1,467 (40.7)	Ref.	
3-5 days	621 (44.5)	1,586 (44.1)	0.81 (0.72-0.93)	0.003
≥ 6 days	74 (5.3)	547 (15.2)	0.28 (0.21-0.36)	<0.001

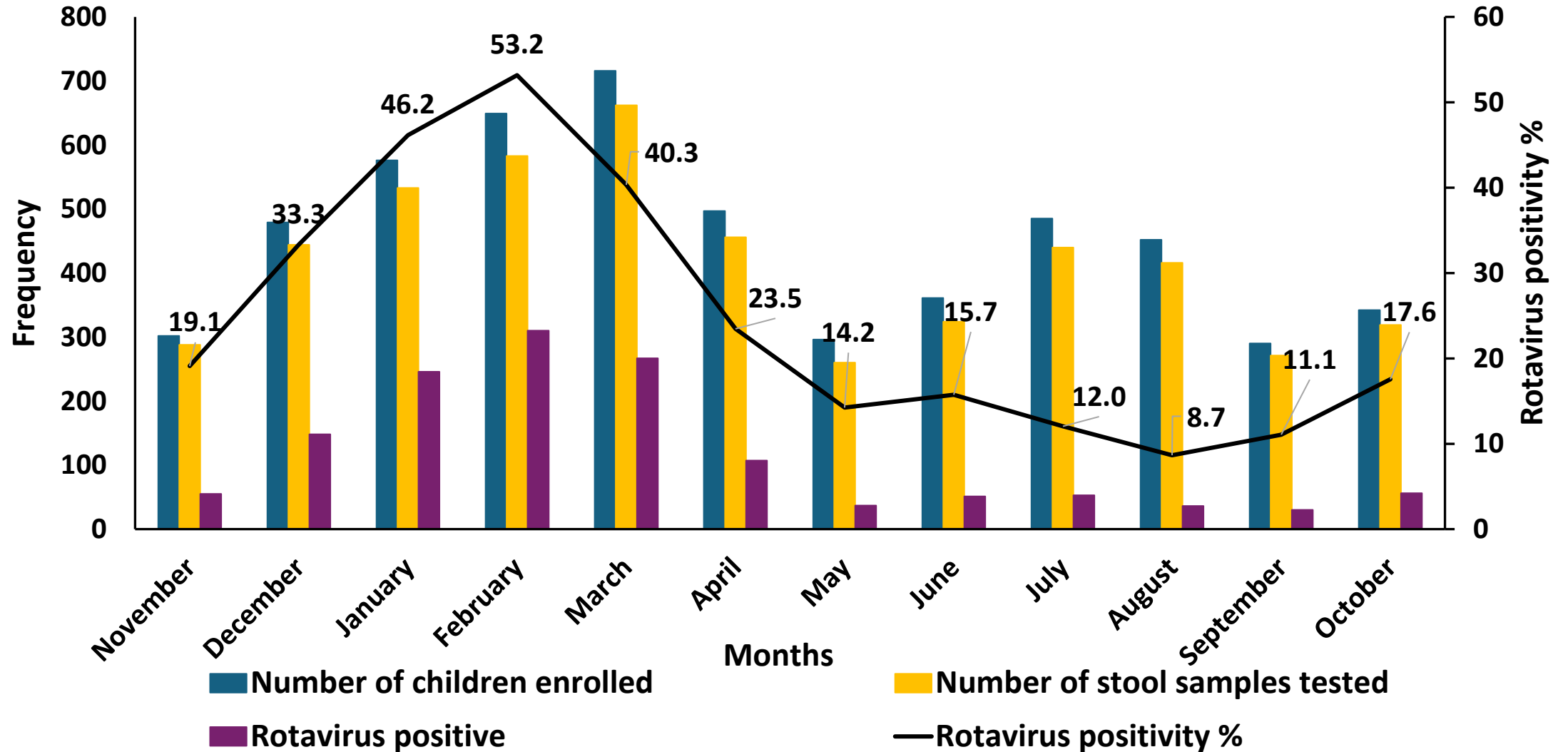
Clinical severity, vaccination & RV positivity

	Rotavirus positive, n=1,396 (%)	Rotavirus negative, n=3,600 (%)	OR (95% CI)	p
Based on modified Vesikari score (N=4,996)				
Mild-moderate (0-10)	283 (21.7)	1,269 (36)	Ref.	<0.001
Severe-very severe (11-20)	1,020 (78.3)	2,255 (64)	2.02 (1.74-2.35)	
Vaccinated with ROTASIIL (N=4,913)				
Unvaccinated	353 (28.1)	814 (24.7)	Ref.	0.020
Received at least one dose	905 (71.9)	2,482 (75.3)	0.84 (0.72-0.97)	
Vaccinated with any brand of rotavirus vaccine (N=4,996)				
Unvaccinated	353 (25.3)	814 (22.6)	Ref.	0.045
Received at least one dose	1,043 (74.7)	2,786 (77.4)	0.86 (0.74-0.99)	

Nutritional status & RV positivity (N=4,996)

	Rotavirus positive n=1,396 (%)	Rotavirus negative n=3,600 (%)	OR (95% CI)	p
Wasting (WHZ score)				
Absent	992 (71.1)	2,429 (67.5)	Ref.	0.014
Present	404 (28.9)	1,171 (32.5)	0.84 (0.73-0.96)	
Underweight (WAZ score)				
Absent	980 (70.2)	2396 (66.6)	Ref.	0.014
Present	416 (29.8)	1204 (33.4)	0.84 (0.73-0.96)	
Malnutrition (MUACZ score)				
Absent	1,156 (82.8)	2,785 (77.4)	Ref.	<0.001
Present	240 (17.2)	815 (22.6)	0.70 (0.60-0.83)	

Seasonality & RV positivity (N=5,445)



Conclusions

- Rotavirus remains a significant contributor to pediatric diarrheal morbidity in India, even in the post-vaccine era.
- Post vaccine rollout, positivity is observed among partially vaccinated children and those in their second year of life.
- Vaccination may have reduced the risk of rotavirus infection, yet continued and strengthened surveillance, improved vaccine coverage, implementing preventive measures, and seasonal preparedness are crucial in reducing long term morbidity and mortality associated with rotavirus infections.

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Thank You!