

Advantages of ROTAVAC[®]

	ROTAVAC [®]	Other RV vaccines
Quick administration	< 10 seconds	Takes longer
Hassle-free handling	No reconstitution Easy flip & tear off seal Easy flow (low viscosity)	Needs reconstitution Complex handling Highly viscous
Low volume	0.5 mL (5 drops) / dose Less cold chain space	Up to 2 mL / dose More cold chain space
Better compliance	Lower volume No wastage during administration No spitting up / vomiting	Larger volume Wastage Spitting up / vomiting
Better taste	No buffer: Sweet taste	Buffer present: Altered taste
Stability	Stable at -20°C and 5°C, Stable without buffer	? Not stable without buffer

Publications

THE LANCET

Efficacy of a monovalent human-bovine (116E) rotavirus vaccine in Indian infants: a randomised, double-blind, placebo-controlled trial

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Background: Rotavirus is a common cause of severe dehydrating gastroenteritis in developing countries. Safe, effective, and affordable vaccines are needed in these countries. We aimed to assess the efficacy and tolerability of a monovalent human-bovine (116E) rotavirus vaccine in low-resource urban and rural settings.

Methods: In a randomised, double-blind, placebo-controlled trial, we vaccinated 116E rotavirus vaccine or placebo in 116E rotavirus vaccine in Indian infants aged 6–12 weeks. The primary endpoint was the number of rotavirus gastroenteritis (RVGE) episodes in the first 12 months of life. Secondary endpoints included the number of hospitalisations, deaths, and quality of life. The trial was registered with ClinicalTrials.gov, NCT01101650.

Findings: In the primary endpoint analysis, the 116E rotavirus vaccine significantly reduced the number of RVGE episodes (mean 1.1 vs 2.1, p < 0.001) and hospitalisations (mean 0.4 vs 0.8, p < 0.001) compared with placebo. The vaccine was well tolerated, with no serious adverse events.

Conclusion: The 116E rotavirus vaccine is safe and effective in Indian infants, significantly reducing the burden of RVGE and hospitalisations. This vaccine should be widely available in low-resource settings.

Interpretation: The 116E rotavirus vaccine is a safe and effective option for preventing RVGE in Indian infants. It is a significant step towards reducing the burden of this common childhood illness.

Future research: Further studies are needed to assess the long-term efficacy and safety of the 116E rotavirus vaccine in different settings and populations.

References: 1. The Lancet. Published online March 12, 2014. [http://dx.doi.org/10.1016/S0140-6736\(13\)62630-6](http://dx.doi.org/10.1016/S0140-6736(13)62630-6). 2. The Journal of Infectious Diseases. 2005; 192:530–5. 3. JOURNAL OF CLINICAL MICROBIOLOGY, JULY 1994, p. 1820–1822. Vol. 32, No. 7. 4. The Journal of Infectious Diseases. 2009; 200:421–9. 5. <http://www.path.org/> <http://vod.createsend1.com/> <http://ViewEmail/r/4A89B511929E52540E23F0FEDD39386C0A480989765E76023466C846>. 6. www.frontline.in June 28, 2013. 7. www.sciencemag.org on May 31, 2013. VOL 340.



August 4, 2014
Rotavirus technical experts meet to prioritize intussusception research agenda
WHO Global Advisory Committee on Vaccine Safety recommends further use of ROTAVAC[®]

MAJOR ARTICLE
Development of Candidate Rotavirus Vaccines Derived from Neonatal Strains in India
Rajeev I. Glass, Mahesh K. Bhan, Pratima Ray, Rajiv Bhat, Umesh D. Parashar, Harry Greenberg, C. Durga Rao, Nita Bhandari, Yvonne Muliyil, Richard L. Ward, David E. Borczyk, and Jon R. Gentsch¹

The need for a rotavirus vaccine in India is based on the enormous burden associated with the 100,000 deaths due to rotavirus diarrhea that occur annually among Indian children. Two rotavirus strains identified during nosocomial outbreaks of rotavirus infection in New Delhi and Bangalore, India, more than a decade ago are being developed as live oral vaccines. Infected newborns had no symptoms, shed virus for up to 2 weeks after infection, mounted a robust immune response, and demonstrated protection against severe rotavirus diarrhea after reinfection. The 2 strains are naturally occurring bovine-human reassortants, identified as having a P11[5]G10 genotype. The strains have been prepared as pilot lots for clinical trials in Indian infants in India. This unique project, which is developing a new rotavirus vaccine in India with the introduction of rotavirus vaccines in India.

In India, diarrhea is a leading cause of illness and death among children <5 years old. Efforts to decrease the number of deaths of diarrheal disease through prophylaxis and improvements in oral rehydration therapy through partially successful, have not been sufficient. Because every child in India will become infected with rotavirus during the first few years of life, it is estimated that 23 million children will be infected each year with rotavirus.

Characterization of Rotavirus Strains from Newborns in New Delhi, India
BIMAL K. DAS, JON R. GENTSCH, HELEN G. CICIRELLI, PATRICIA A. WOODS, AARTI GUPTA, MADHUMATI RAMACHANDRAN, RAMAKRISHNA KUMAR, M. K. BHAN, and ROGER I. GLASS¹

Between 1986 and 1993, 72% of rotavirus strains isolated from newborns at five hospitals in New Delhi, India, had long electrophoretic, subgroup 11 VP6 antigens and G and P genotypes (G₁₁P₁₁) identical to those of genotype strain 116E. A novel strain with a G₁₁P₁₁ genotype, representing 13% of the isolates, was identified. These results demonstrate that G₁₁P₁₁ and G₁₁P₁₁ rotavirus strains are common in nurseries in New Delhi. This finding indicates that the 116E strain is a reassortant of the G₁₁P₁₁ and G₁₁P₁₁ strains that are present in live of six six months of age. The 116E strain is a reassortant of the G₁₁P₁₁ and G₁₁P₁₁ strains that are present in live of six six months of age.

References

1. The Lancet. Published online March 12, 2014. [http://dx.doi.org/10.1016/S0140-6736\(13\)62630-6](http://dx.doi.org/10.1016/S0140-6736(13)62630-6).
2. The Journal of Infectious Diseases. 2005; 192:530–5.
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ROTAVAC[®]

Oral Rotavirus Vaccine 116E, Live Attenuated



Store at -20°C.
Transport at 5°C ± 3°C.
It can be stored up to 6 months at 5°C ± 3°C at any time during shelf-life.

- Efficacy** nRV (natural ROTAVAC[®]) similar to reassorted mono (RV1)/multivalent (RV5)
- Long-term Efficacy** nRV is better than reassorted mono (RV1)/multivalent (RV5)
- Non-Interference** Can be safely given with UIP childhood vaccines
- Breast Feeding** No interference with breast milk
- Safety** No vaccine related intussusception
- Dose Schedule**
 - 1st 6th Week
 - 2nd 10th Week
 - 3rd 14th Week



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Hon'ble Prime Minister dedicates ROTAVAC[®] to the Nation



Lead Innovation

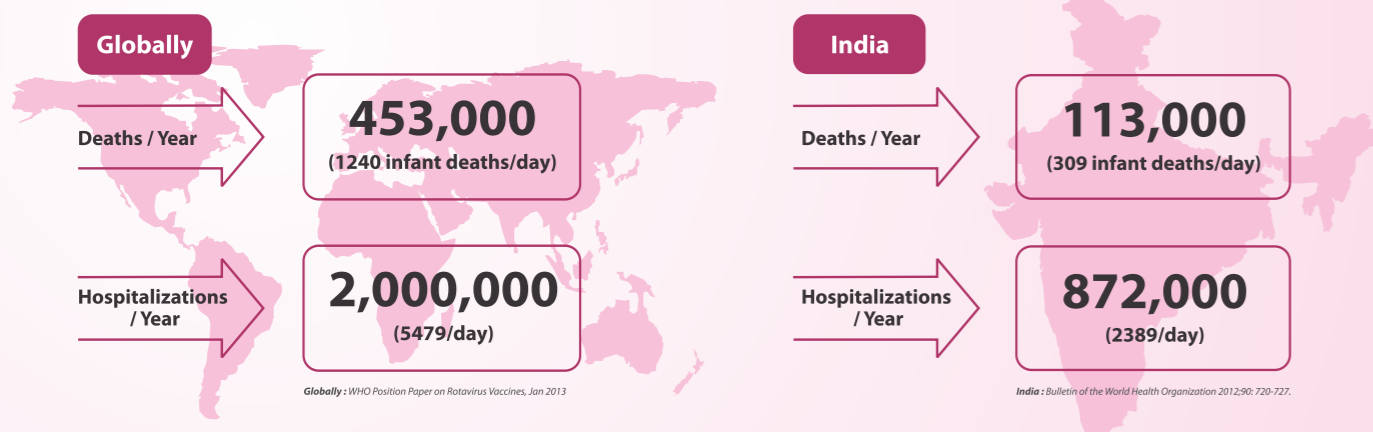
For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only. Revise 05/2015

NATURALLY

ATTENUATED

ROTAVAC[®]

Impact of Rotavirus Infection



Protect your baby with Nature's gift

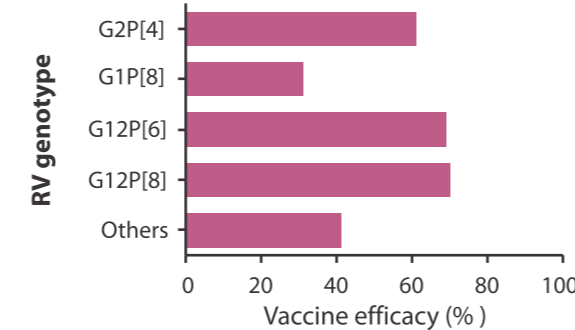
5 sweet drops of
ROTAVAC[®]

Oral Rotavirus Vaccine 116E, Live Attenuated

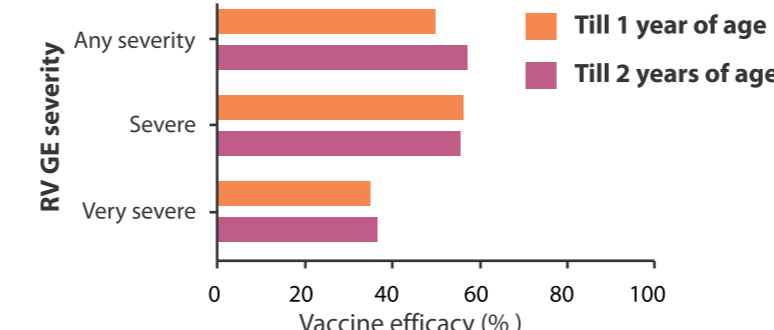
India's 1st Social Innovation Project for Public Healthcare

India's 1st Phase III efficacy clinical trial

ROTAVAC[®] vaccine broad cross-protection

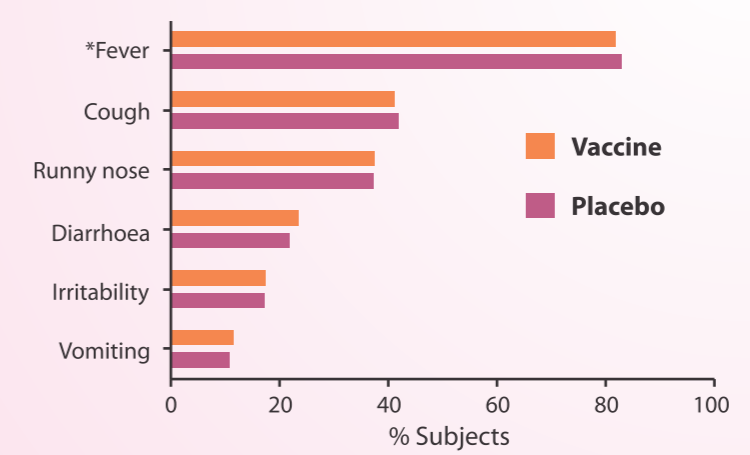


Long-term Efficacy

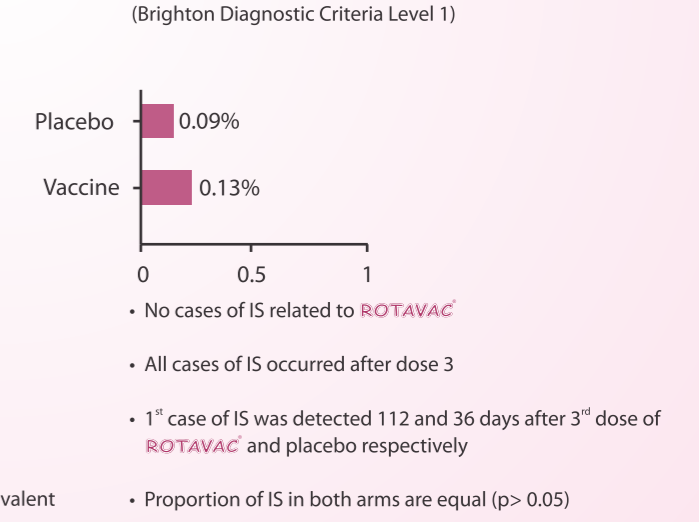


RVGE, rotavirus gastroenteritis. Scored as per Vesikari scores; >11- Severe, Requiring hospitalization-Very severe.

Vaccine attributable adverse events



Intussusception (IS)



ROTAVAC[®] is efficacious in preventing severe rotavirus diarrhoea in low resource settings / countries

Trial Country	Vaccine	Dose Schedule	Efficacy 1 st year of life	Efficacy 2 nd year of life	Overall Efficacy 1 st two years of life
LOW INCOME SETTINGS					
Malawi	RV1	2 doses	49%	3%	34%
Malawi	RV1	3 doses	50%	33%	42%
Africa (Ghana, Kenya, Mali)	RV5	3 doses	64%	20%	39%
Bangladesh	RV5	3 doses	46%	39%	43%
India	ROTAVAC [®]	3 doses	56%	49%	55%

Kang, et. al Vaccine 325(2014) A171-A171; Bhandari et. al Vaccine 325 (2014) A110-A116

ROTAVAC[®] vaccine developed with Indian and Global partnerships

