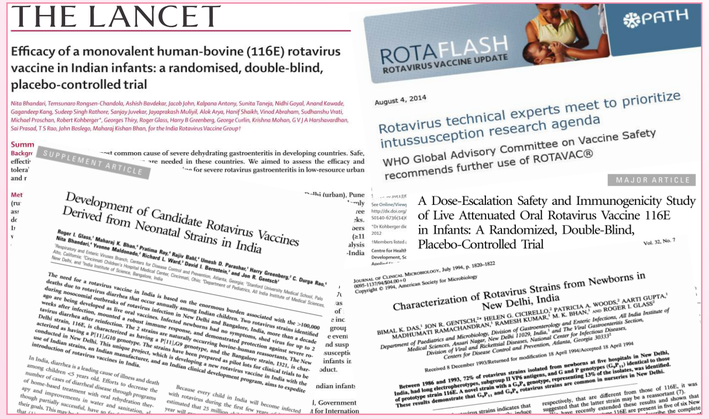
Advantages of ROTAVAC®

	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

ROTAFLASH
ROTAVIRUS VACCINE UPDATE
PATH

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

SUPPLEMENT ARTICLE

Development of Candidate Rotavirus Vaccines Derived from Neonatal Strains in India

A Dose-Escalation Safety and Immunogenicity Study of Live Attenuated Oral Rotavirus Vaccine 116E in Infants: A Randomized, Double-Blind, Placebo-Controlled Trial

Characterization of Rotavirus Strains from Newborns in New Delhi, India

References

1. www.thelancet.com Published online March 12, 2014 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://vad.createsend1.com /t/ViewEmail/r/4A899B511929E525254DEF23F30FEDED/39386CC0A4809BB9765E7602346EC846
6. www.frontline.in June 28, 2013
7. www.sciencemag.org on May 31, 2013 VOL 340
8. Bhan MK, et al. Protection conferred by neonatal rotavirus infection against subsequent rotavirus diarrhea. The Journal of infectious diseases 1993; 168:282–7.
9. Das BK, et al. Characterization of rotavirus strains from newborns in New Delhi, India. Journal of clinical microbiology 1994; 32:1820–2.
10. Glass RI, et al. Development of candidate rotavirus vaccines derived from neonatal strains in India. The Journal of infectious diseases 2005; 192 Suppl 1:S30-5.
11. Bhandari N, et al. A dose-escalation safety and immunogenicity study of live attenuated oral rotavirus vaccine 116E in infants: a randomized, double-blind, placebo-controlled trial. The Journal of infectious diseases 2009; 200:421–9.
12. Kuhlmann FM, et al. Accelerating next-generation vaccine development for global disease prevention. Science 2013; 340:1232910.
13. Bhandari N, et al. Efficacy of a monovalent human-bovine (116E) rotavirus vaccine in Indian infants: a randomised, double-blind, placebo-controlled trial. Lancet 2014; 383:2136–43.
14. Bhan MK, et al. Team science and the creation of a novel rotavirus vaccine in India: a new framework for vaccine development. The Lancet 2014; 383:2180–3.
15. Bhandari N, Rongsen-Chandola T, Bavdekar A, et al. Efficacy of a monovalent human-bovine (116E) rotavirus vaccine in Indian children in the second year of life. Vaccine 2014; 32 Suppl 1:A110–6.

Bharat Biotech
Lead Innovation

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 — *n*RV (natural ROTAVAC®) similar to reassorted mono (RV1)/multivalent (RV5)

Long-term Efficacy — *n*RV 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

Bharat Biotech
Lead Innovation
www.bharatbiotech.com

Distributed by:

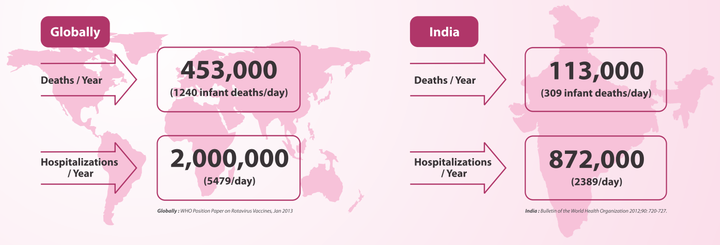
Hon'ble Prime Minister dedicates ROTAVAC® to the Nation

For the use of a Registered Medical practitioner or a Hospital or a Laboratory only.

Bharat Biotech
Lead Innovation

NATURALLY ATTENUATED ROTAVAC®

Impact of Rotavirus Infection



Globally : *WHO Position Paper on Rotavirus Vaccines, Jan 2013*

India : *Bulletin of the World Health Organization 2012;90: 720-727.*

ROTAVAC® vaccine developed with Indian and Global partnerships

Department of Biotechnology, Ministry of Science and Technology · National Institutes of Health · CDC · Bharat Biotech · Stanford University · PATH, A catalyst for global health · Department for International Development · HRD SAS · The Research Council of Norway · thsti

Bharat Biotech, Lead Innovation

Protect your baby with Nature's gift

5 *sweet drops of*

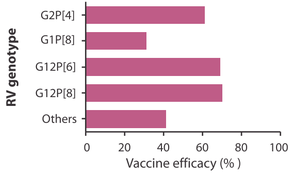
ROTAVAC®

Oral Rotavirus Vaccine **116E,** Live Attenuated

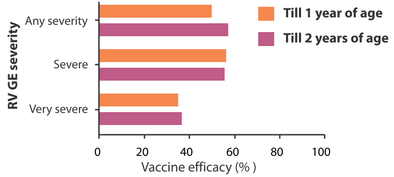
India's 1st Social Innovation Project for Public Healthcare

India's 1st Phase III efficacy clinical trial

ROTAVAC® vaccine broad cross-protection



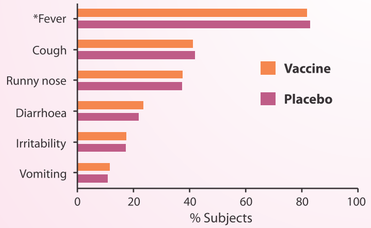
Long-term Efficacy



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

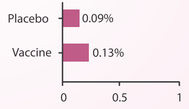
Bharat Biotech, Lead Innovation

Vaccine attributable adverse events



*Fever likely due to concomitant childhood vaccines such as Pentavalent

Intussusception (IS)
(Brighton Diagnostic Criteria Level 1)



- No cases of IS related to ROTAVAC®
- All cases of IS occurred after dose 3
- 1st case of IS was detected 112 and 36 days after 3rd dose of ROTAVAC® and placebo respectively
- Proportion of IS in both arms are equal (p> 0.05)

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

Trial Country	Vaccine	Dose Schedule	Efficacy 1st year of life	Efficacy 2nd year of life	Overall Efficacy 1st 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

Bharat Biotech, Lead Innovation