

## India finally gets its magical vaccine

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India has realized its dream of developing an indigenous vaccine against the rotavirus, the main cause behind diarrhoea that results in 10 lakh hospitalizations and kills nearly 80 thousand children under the age of 5 years. Developed by Hyderabad-based Bharat Biotech, the oral rotavirus vaccine, ROTAVAC has been proved to be safe and effective in preventing rotavirus diarrhoea.

The vaccine was launched on March 09, 2015 by the Prime Minister, Mr Narendra Modi whose enthusiasm was visible given his focus on the 'Make in India' initiative. The PM lauded the vaccine as an example of India's capabilities for high-end research and development; manufacture of sophisticated pharmaceutical products in India; and an effective public private partnership model for finding affordable solutions to societal challenges. "The development of the rotavirus vaccine will inspire higher levels of research, development and manufacturing activities in India, not just in medical science, but also in other advanced areas of science and technology," remarked Mr Modi.

This announcement fulfilled Bharat Biotech's promise of a \$1/ dose vaccine to governments in low income countries. The company has received commercial licensure and the vaccine is safe to use. The company that was involved in the development and production of the vaccine was selected in 1997-1998 by the India-US Vaccine Action Program and the standard government procedures. This is the third such vaccine available globally against Rotavirus and, at the current prices, the cheapest. "ROTAVAC represents the successful research and development of a novel vaccine from the developing world with global standards," said Dr Krishna M Ella, chairman and managing director of Bharat Biotech. "ROTAVAC is a testament of our strong vision and commitment to develop affordable health care solutions for infectious diseases." As per Dr Ella, "A novel vaccine innovated in India, developed in India and made in India, is a big boost to the 'Make in India' initiative by the government. The launch fortifies our mission to identify public health problems and make affordable life-saving vaccines available to children wherever they are born."

It was a belief that was shown some twenty eight years ago and might have been looked at with a lot of scepticism back then. But it was Dr MK Bhan, former secretary of the Department of Biotechnology (DBT) whose dream of manufacturing an indigenous rotavirus vaccine one day kept the efforts multiplying and the project expanding.

Dr Bhan termed the launch as a culmination of decades of selfless efforts by researchers across the globe. He added, "Ideas are good only when they are pursued to the very end. The Rotavac story is a good mix of innovation and purpose."

Dr Harry Greenberg, associate dean, Stanford University added, "The ROTAVAC project is a beautiful example of the great power of team science. The vaccine is a culmination of a very large and disparate group of people and organizations all working together for a common goal: to produce a safe, effective and affordable vaccine to prevent severe rotavirus associated diarrhoea in Indian children."

"The randomized, double-blind, placebo-controlled phase III clinical trial enrolled 6,799 infants in India (aged six to seven weeks at the time of enrolment) at three sites-the Center for Health Research and Development, Society for Applied Studies (SAS) in New Delhi; Shirdi Sai Baba Rural Hospital, KEM Hospital Research Center in Vadu, Pune; and Christian Medical College (CMC) in Vellore. Infants enrolled in the study received ROTAVAC and the Universal Immunization Program (UIP) vaccines, including Oral Polio Vaccine (OPV). When the immune responses to OPV were tested, the result showed that infants receiving OPV at the same time as vaccine generated comparable immune responses to all three polio serotypes as the infants receiving OPV without ROTAVAC; this result supports the concurrent administration of OPV and ROTAVAC."

### **Innovative PPP**

The interesting fact about the vaccine is that it was developed through a unique social innovation partnership that brought together the experience and expertise of Indian and international researchers as well as the public and private sectors. The vaccine development partnership was supported by DBT, the Bill and Melinda Gates Foundation, the Research Council of Norway, and the UK Department for International Development.

Bharat Biotech invested important technical, manufacturing, and financial resources towards vaccine development. The support laboratory was the Translational Health Science and Technology Institute. Quintiles was responsible for several aspects of the trial including medical monitoring, data management, site monitoring, pharmacovigilance, and biostatistics. Good Clinical Practice compliance of the clinical trials was audited by ANTHA Clinical Quality Assurance.

The rotavirus vaccine development despite having taken decades to materialize, showcases India's biotech potential. At the same time, while half of the battle has been already won, we cannot afford to be satisfied only by having the vaccine. Now starts the second stage of its implementation in the Universal Immunization Program (UIP) and awareness among masses which of course is a herculean task in itself. Yet the best part is that we already have existing networks from polio campaign which can be pressed in to action with renewed vigour.

### **Journey of Rotavac:**

1985-86: Dr MK Bhan discovers strain, 116E during his routine testing at the All India Institute of Medical Sciences (AIIMS), New Delhi. He partners with Dr Roger Glass, a diarrhoeal expert working then at the CDC's rotavirus laboratory. Around the same time, Dr Durga Dass discovers another strain, I321 at the Indian Institute of Science (IISc), Bangalore. He collaborates with Dr Harry Greenberg of Stanford University for further research.

1987: Both the naturally occurring, weakened strains studied by the two independent research teams working parallelly under the Indo-US Vaccine Action Program, bilateral program implemented since 1987 by DBT and NIH.

2000: Consortium of partners including Bharat Biotech, CDC, NIH, AIIMS, Stanford University, and IISc, submitted a proposal to PATH and DBT for support to move the two vaccine candidates through production, testing and surveillance.

2003: Partners meet to discuss the clinical studies strategies of the 116E and 1321 vaccine lots. After clearance of protocols for the phase I, first Indian trials began at AIIMS.

2004-2005: The trial results showed the 116E strain being more effective, providing immunity to 36.6 percent of recipients as compared to 15.4 percent of I321 recipients. On the basis of results, focus was completely put on the 116E strain for further development.

2006: The consortium initiated combined phase Ib/IIa dose escalation study of the 116E vaccine candidate in infants at the National Institute of Immunology, Delhi.

2008: The conclusion of Phase Ib/IIa trial showed no identified safety concerns and demonstrated robust immune response in 89 percent of infants.

â? 2011: The Phase III trials of 116E (now named Rotavac) on 6,799 infants began across three sites in India.

â? 2013: The data from trial results presented at the international symposium on 'Rotavirus Vaccines for India-The Evidence and the Promise', showed Rotavac to have an excellent safety and efficacy profile.

â? 2015: Vaccine launched and set to be implemented in national immunization programme.