

Indigenously developed Rotavirus Vaccine - ROTAVAC®

The low cost indigenously developed rotavirus vaccine - ROTAVAC shall be given to every child across all 37 states/UTs as per decisions of Union Ministry of Health and Family Welfare in order to expand rotavirus vaccine to the entire country. In 2016, India introduced its first indigenously developed rotavirus vaccine in national immunization programme in a phase manner after thorough consideration of its effectiveness in preventing severe rotavirus infection.



India's first indigenously developed vaccine - ROTAVAC

The primary aim of introducing the ROTAVAC in universal immunization programme was to identify rotavirus infection cases among hospitalized children (age less than 5 years) for acute gastroenteritis (AGE) and circulating rotavirus genotypes pre- and post vaccination using a robust surveillance system. Other objectives were to measure the changes in proportion of AGE including all changes in same setup, and to establish the efficacy of completed series of ROTAVAC against laboratory confirmed severe rotavirus AGE cases. The secondary objectives of the programme were to determine the vaccine's effectiveness against specific rotavirus genotypes, and waning of vaccine's effectiveness throughout the surveillance period.

The phase wise trails of rotavirus vaccination program achieved national coverage in September 2019. On 19th September 2019, Government of India released a white paper on the safety of rotavirus vaccine which highlighted the need for collating safety data from all sources in the post-marketing period, routine data collection and special studies conducted under Smart Safety Surveillance (3S) project. The 3S project enabled synthesis of multiple data sets, with high data quality from the sentinel surveillance systems, and provided reassurance regarding the safety of

the ROTAVAC vaccine. India is trying to strengthen the collaboration among key collaborators to ensure high levels of vigilance throughout rotavirus vaccination program.

ROTAVAC was developed by Hyderabad-based Bharat Biotech Limited and Pune-based Serum International Limited. The core funding for development of ROTAVAC vaccine was given by the Gates Foundation, PATH and BIRAC-Department of Biotechnology (DBT), Government of India. The vaccine successfully completed its Phase III clinical trials at three sites, the Centre for Health Research and Development, Society for Applied Studies (SAS), New Delhi; Shirdi Sai Baba Rural Hospital, KEM Hospital Research Centre, Pune; and Christian Medical College (CMC), Vellore. The data from clinical trial have shown that ROTAVAC® has got excellent safety and efficacy profile. In January 2018, it got World Health Organisation (WHO) “pre-qualification” and vaccine could now be sold internationally to other countries like Africa and South America.

Rotavirus infection accounts for 39% of under-five diarrhoeal deaths around the globe and 22% of these deaths occur in India only. Rotavirus invasion erodes the villus lining the small intestines and infects enterocytes. Such withering of intestinal cell lining induces diarrhoea through the destruction of absorptive enterocytes. The ROTAVAC vaccine provides protection against rotavirus infection and reverses the damage and provides immunity against the infection. The rotavirus-specific immunoglobulin-A plays a role both in protection against infection and recovery after infection. The vaccine can be safely co-administered with three doses of pentavalent vaccine and oral polio vaccine (OPV) and it is also well tolerated when administered along with the routine childhood vaccines at 6, 10 and 14 weeks of age.

Since the global demand for rotavirus vaccines is increasing because more countries are expanding their immunization programmes. The lack of need of a buffering agent, low dose volume (0.5mL), non-interference with other parallel administered vaccines, and conformance with WHO standards provide ROTAVAC the potential for widespread global usage and success.

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