

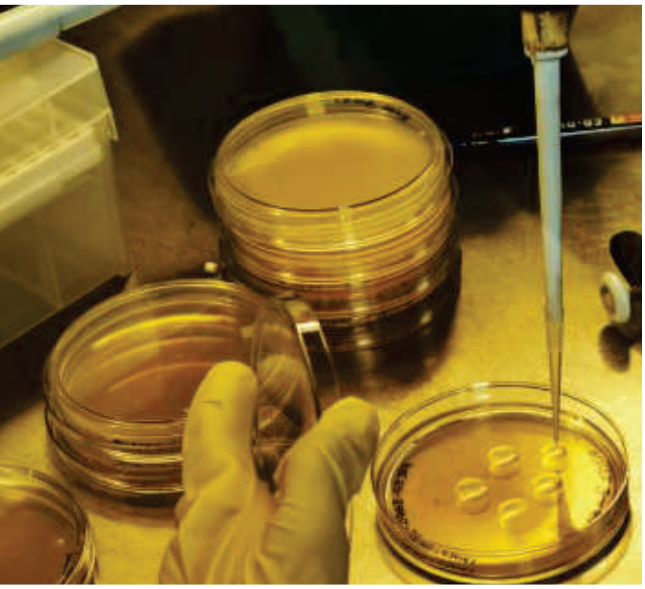

BHARAT

BIOTECH

Lead Innovation

› VISION

To offer affordable, safe and effective healthcare solutions to combat mankind's dreaded illnesses and to thus eradicate or atleast control their occurrence in the years to come.

› MISSION

We seek to address the health care needs of the 7 billion people in the emerging markets by driving innovation and being a frontrunner in research and development of new vaccine and bio-therapeutics.

HISTORY

Established	: 1996
Founders	: Dr. Krishna & Ms. Suchitra Ella
Business Line	: Vaccines and Bio-therapeutics
First Project	: Recombinant Hepatitis B Vaccine
Investment	: US $ 3.5 Million
Personnel	: Over 1500
Accreditations	: WHO, Korean FDA, ANVISA, and others
Innovation	: More than 110 global patents

HISTORY

OUR EXCELLENCE

- Creating innovative vaccines and bio-therapeutics
- Over 3 billion vaccines delivered globally
- More than 110 global patents
- Supplying to over 165 countries
- WHO- Approved, GMP- Certified manufacturing facilities
- World's first WHO-Prequalified Typhoid Conjugate Vaccine
- World's first eco-friendly recombinant Hepatitis-B vaccine (free of Cesium Chloride and Thiomersal)
- World's first WHO-Prequalified Rotavirus vaccine from a naturally attenuated strain

INNOVATION

› Our focus on developing world countries like Asia, Africa, South America

› Neglected Infectious diseases

› Ease of administration

› Reduction in cold chain foot print

› Ease of distribution and delivery

› Product pricing

Production

OUR PRODUCTS

Recombinant Vaccines

- REVAC-B+ - Recominant Hepatitis B vaccine
- REVAC-B mcf - Mercury and Cesium Chloride free Recombinant Hepatitis B vaccine
- COMVAC - 4 - Diptheria, Tetanus, Pertussis (whole cell), Hep B (rDNA) Vaccine
- COMVAC-5 - Diptheria, Tetanus, Pertussis Pertussis (whole cell), Hep B (rDNA) and Hemophilis Type -B Conjugate Vaccine (Absorbed)

Viral Vaccines

- INDIRAB - Rabies Vaccine
- JENVAC - Japanese Encephalitis Vaccine
- ROTAVAC - Raotavirus Vaccine
- HNVAC - Influenza a (H1NI1) Vaccine
- BIOPOLIO - Polio vaccine

Bacterial vaccines

- TYPBAR TCV - Typhoid Conjugate Vaccine
- COMVAC - 3 - Diptheria, Tetanus, Pertussis Vaccine
- BIOHIB - Indegenously developed vaccine for haemophilus influenzae type-b bacteria (Hib)

Bio-therapeutics

- REGEN-D - Recombinant Human Epidermal Growth Factor
- SLVRGEN - Recombinant Human EGF with Silver Sulfadiazine and Chlorhexidine Gluconate
- BIOGIT - Gastrointestinal (GI) friendly probiotic yeast
- ZELECT - Oral Rehydration Salts (ORS)

IN THE MEDIA

nature

Treatments that made headlines in 2018

The World Health Organization approved a vaccine against typhoid fever called Typbar TCV, short for typhoid conjugate vaccine. It is the only vaccine deemed safe enough for use in infants starting at six months of age. The vaccine is produced by Hyderabad, India-based Bharat Biotech and is the first conjugate vaccine - a vaccine in which a weak antigen is attached to a strong antigen to elicit antibody responses - against the bacterial disease that affects up to 20 million people annually. The approval came after the vaccine was tested in a trial in which volunteers ingested a dose fo *Salmonella typhi*, the bacterium that causes typhoid. The trial found that 87% of those sorted into the vaccine group were protected against the disease (*Lancet* 390, 2472 - 2480, 2017).

- Dec 2018

The New York Times

They Swallowed Typhoid Bacteria - On Purpose

More than 100 residents of Oxford, England, took part in a trial of a new typhoid vaccine. Typbar TCV is the only effective vaccine that is also safe for infants, and is already used widely in India.

- Sep 2017

THE LANCET

Typhoid Vaccine Development With A Human Challenge Model

The most advanced conjugate vaccine, Typbar-TCV® (Vi-TT) is licensed in India where it has been shown to elicit robust serum Vi antibody responses after only one dose, even in Indian infants as young as 6 months old. 112 participants were enrolled in this trial, which showed that the Vi-TT is well tolerated, achieved 100% seroconversion of Vi antibody (versus 89% for Vi-PS), and stimulated significantly higher geometric mean titres than did unconjugated Vi-PS. Jin and colleagues report that the efficacy of Vi-TT was 87.1%

- Sep 2017

GLOBAL CITIZEN

The 10 Biggest Global Health Wins of 2018

The Development of a New Rotavirus Vaccine Was Approved

In January, vaccine manufacturer Bharat Biotech announced that the World Health Organization (WHO) had approved the development of a new rotavirus vaccine, ROTAVAC - which costs only $1 per dose.

A vaccine this contagious virus could prevent millions of deaths as rotavirus and other diarrheal diseases are the second biggest killer of children under 5 years old.

- Dec 2018

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thebmj

Multidrug resistant enteric fever in South Asia: unmet medical needs and opportunities

Vaccination can have an important role in reducing the disease burden and stalling the emergence of resistant strains. Until recently, two typhoid vaccines have been available: an oral vaccine (Ty21a vaccine) supplied in enteric coated capsules taken once daily for three days, and the injectable Vi polysaccharide vaccine (ViCPS vaccine) given intramuscularly in a single dose. The protective efficacy wanes over time, and re-vaccination is recommended every three years. Neither vaccine is recommended in children younger than 2 years, making it difficult to incorporate them into routine vaccination programmes in endemic settings, and so vaccines have been largely used in travellers to low and middle income countries.

In January 2018, WHO prequalified a conjugated Vi polysaccharide vaccine.

Typbar-TCV, indicating it meets the required standards of safely, efficacy, and quality to be rolled out in routine childhood immunisation programs in endemic countries.

The vaccine, which was developed by the Indian drug company Bharat Biotech, has longer and higher levels of immunogenicity than the ViCPS vaccine and is safe to use in infants older than 6 months. In October 2017, the Strategic Advisory Group of Experts (SAGE) on immunisation recommended routine use to the vaccine in typhoid endemic countries as a single dose in children aged 6-23 months, and for catch-up vaccination in children aged 2-15 years.

- Jan 2019

IN THE MEDIA

The NEW ENGLAND JOURNAL of MEDICINE

Extensively Drug-Resistant Typhoid - Are Conjugate Vaccines Arriving Just in Time?

Circumstances have changed in several ways that make vaccination more attractive. First, a tetanus-toxoid conjugated Vi- polysaccharide typhoid vaccine (Typbar TCV; Bharat Biotech), developed and produced in India, was prequalified by the WHO in January 2018 after demonstrating high and sustained immunogenicity with noninferior efficacy to Vi polysaccharide vaccine in a human challenge model. This vaccine is immunogenic in children as young as 6 months of age, which could enable its use in routine immunization programs.

The good news is that an effective typhoid conjugate vaccine is now available and can be used to augment typhoid-control efforts. The Typbar TCV vaccine is now being used in the outbreak response in Hyderabad, though the strain had already spread beyond the vaccine target area and may continue to disseminate.

- Oct 2018

The Economist

A newly revived vaccine may deal a death blow to typhoid fever

Now the Gates Foundation has plucked Typbar-TCV from obscurity and pushed it through the research and testing necessary for it to be used everywhere.

One of the first of those tests was conducted by the Oxford Vaccine Group (OVG), a research organisation in Britain, in 2017. Andrew Pollard, OVG's boss, recruited 100 adult volunteers, vaccinated them and then gave them a drink laced with live *S. typhi.* Britain was a good place to do this because typhoid is essentially extinct there, so participants had no existing immunity. Antibiotics were on hand to treat those who succumbed, but most did not. This and subsequent experiments have shown the vaccine to be almost 90% effective and, crucially, safe for use in children as young as six months.

The new vaccine has also been warmly welcomed by GAVI, an international health organisation formerly known as the Global Alliance for Vaccines and Immunisation.

Other places where the vaccine could be deployed include Bangladesh, Ghana, India, Nepal, Nigeria and Uganda.

- Feb 2019

THE ECONOMIC TIMES

Bharat Biotech's Typhoid vaccine gets WHO pre-qualification

Bharat Biotech's Typhoid Conjugate Vaccine (TCV) against typhoid fever has received pre-qualification from the World Health Organization (WHO), the vaccine manufacturer said on Wednesday.

The Hyderabad-based company claims that Typbar TCV is the world's first clinically proven TCV.

The WHO pre-qualification enables the procurement and supplies of this life saving vaccine to UNICEF, the Pan-American Health Organization (PAHO) and GAVI (a vaccine alliance) supported countries.

Typbar TCV has been evaluated in Human Challenge Studies at Oxford University and typhoid conjugate vaccines have been recommended by WHO's Strategic Advisory Group of Experts on Immunization (WHO-SAGE).

Typbar TCV is the first typhoid vaccine, clinically proven to be administered to children from 6 months of age to adults and confers long term protection against typhoid fever, said Dr. Krishna Ella, Chairman and Managing Director of Bharat Biotech.

- Jan 2018

BBC NEWS

Typhoid vaccine (TYPBAR-TCV) set to have 'huge impact'

A new vaccine (Typbar-TCV) that could prevent up to nine-in 10 cases of typhoid fever has been recommended by the World Health Organization.

Experts say it could have a 'huge impact' on the 22 million cases, and 220,000 details, from typhoid each year. Crucially it works in children, who are at high-risk of the infection, unlike other typhoid vaccine. It is hoped the vaccine could eventually help countries eliminate typhoid.

Typhoid fever is caused by *Salmonella typhi* bacteria and patients have, prolonged fever, headache, nausea, loss of appetite, constipation. In one-in 100 cases it cause fatal complications. The bacteria are highly contagious and spread through contaminated food or water.

- Oct 2017

The Telegraph

In March, WHO pre-qualified a new typhoid vaccine, Typbar- TCV, which can be used in children as young as six months old and is more effective than other vaccine.

- 2017

OUR PARTNERS

University of Maryland | University of Oxford | Bill & Melinda Gates foundation

TyVAC Typhoid Vaccine Acceleration Consortium
CENTER FOR VACCINE DEVELOPMENT • OXFORD VACCINE GROUP • PATH

CDC Centers for Disease Control and Prevention | Gavi The Vaccine Alliance

Bill & Melinda Gates foundation | PATH | NIH National Institute of Allergy and Infectious Diseases

Department of Biotechnology
Ministry of Science and Technology
सत्यमेव जयते

Christian Medical College Vellore India | K.E.M. Hospital Pune

The Research Council of Norway

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