## IN THE MEDIA



The world's first conjugate vaccine for typhoid, by Bharat Biotech, was prequalified by WHO and has caught the attention of Gavi, the international Vaccine Alliance.

### nature

In its Yearbook, Nature journal declared Typbar TCV® as one of the treatments that made headlines in 2018.

# The Telegraph

In March, WHO prequalified a new typhoid vaccine, Typbar TCV<sup>®</sup>, which can be used in children as young as six months old, and is more effective than other vaccine.

## The New Hork 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<sup>®</sup> is the only effective vaccine that is also safe for infants, and is already used widely in India.



### THE LANCET

#### TYPHOID VACCINE DEVELOPMENT WITH A HUMAN CHALLENGE MODEL

The most advanced typhoid conjugate vaccine, Typbar TCV® (ViTT), eliciting robust serum Vi antibody responses after only 1 dose 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 with efficacy of 87.1%

### **GLOBAL EFFECTIVENESS STUDY - VACCINE TRIAL KICKS OFF**

Clinical trials of the new Typbar TCV® are being conducted to further evaluate vaccine efficacy and impact of a typhoid conjugate in reducing typhoid burden in endemic countries.

The Board of Gavi, the Vaccine Alliance, approved US\$ 85 million for 2019-20 to support its introduction in developing countries.

Nepal: ~ 25,000 subjects

Malawi: ~ 24,000 subjects

Navi Mumbai (India): ~ 200,000 subjects

#### In partnership with:



MARYLAND



Stanford University



















"Typbar TCV" is a weapon against the high but underappreciated burden of typhoid fever in children and adults."

- Dr. M. K. Bhan, Former Secretary, Department of Biotechnology, Govt. of India

"The WHO prequalification of Typbar TCV® marks an important milestone in the global effort to rid the world of typhoid fever and improve health for some of the most vulnerable populations in the world."

> - Prof. Andrew Pollard, Professor of Paediatric Infection and Immunology, University of Oxford

"With this new vaccine, countries will finally be able to protect millions of children who are most vulnerable to this deadly disease.

- Dr. Anita Zaidi, Director of Vaccine Development, Surveillance, and Enteric and Diarrheal Diseases, **Bill & Melinda Gates Foundation** 

"Typbar TCV® can be incorporated into routine vaccination schedules, giving us the best chance to reach children most at risk for this devastating

- Dr. Kathy Neuzil. Director - Center for Vaccine Development, at the University of Maryland School of Medicine

"The typhoid conjugate vaccine will not only save lives, but also bolster the fight against anti-microbial drug-resistance. Expanding vaccine coverage will play an important role in reducing illnesses and deaths from typhoid. Gavi is looking forward to working with countries to support the introduction of this safe and effective vaccine."

- Dr. Seth Berkley, CEO - Gavi, the Vaccine Alliance





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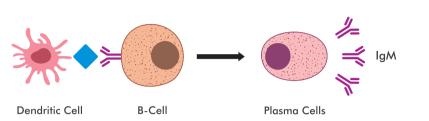


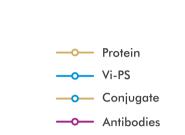
THE WORLD'S 1<sup>ST</sup> WHO PREQUALIFIED TYPHOID CONJUGATE VACCINE

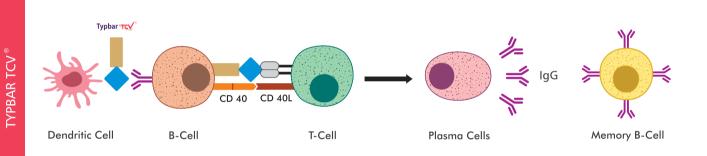
~ 21 MILLION CASES REPORTED PER YEAR

~ 161,000 DEATHS REGISTERED PER YEAR

http://www.who.int/mediacentre/factsheets/typhoid/en/-2018







Mechanism of action of Polysaccharide and Polysaccharide-Protein conjugate vaccines adapted from: P. K. Klouwenberg and L. Bont, (2008) Clinical and Developmental Immunology, Vol. 2008, doi: 10.1155/2008/628963

NO.	PARTICULARS	TYPBAR TCV® (Vi-TT, 25 μg)
1	WHO Prequalified	Yes
2	Immune protection data	Up to 5 years (data as available)
3	Number of subjects, participated in the clinical trials (phase 1 to 4)	
	a. Phase I to III Clinical Trials	~ 1100 participants
	b. Phase IV Clinical Trials	~ 3500 participants
	c. PMS (Post-Marketing Surveillance)	~10,000 participants
4	Interference with MCV & MMR	MCV/MMR does not interfere with TCV. Hence TCV can be administered at 9 months of age
5	Controlled Human Infection Model study	Conducted by University of Oxford, UK, showed vaccine efficacy of 87.1%
6	WHO-SAGE recommendations*	Global usage of Typbar TCV®, as required.
7	US Patent	Granted
8	Vaccine effectiveness & field usage (Ongoing studies)	~ 600,000 subjects from Nepal, Bangladesh, Malawi, Burkina Faso, Pakistan, Navi Mumbai (India)

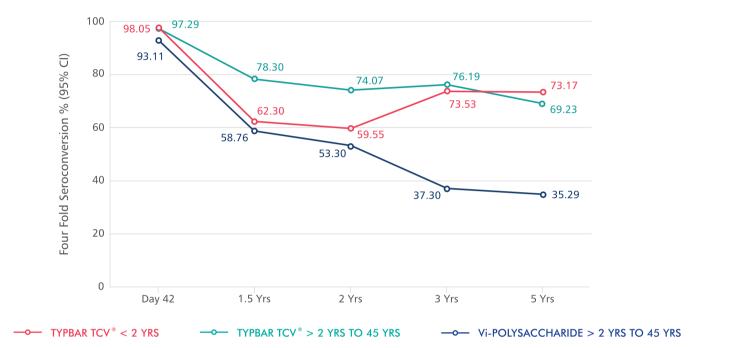
<sup>\*</sup> https://www.who.int/medicines/news/2017/WHOprequalifies-breakthrough-typhoid-vaccine/en/

# Typbar (TCV) - SINGLE DOSE IMMUNOGENICITY & SAFETY DATA

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CONJUGATION
CHEMISTRY
INFLUENCES
IMMUNOGENICITY

### SEROCONVERSION



### AVIDITY INDEX

### POST-MARKETING SURVEILLANCE



### NON-INTERFERENCE STUDY



# THE Typbar TCV ADVANTAGE

- » A single dose of Typbar TCV $^{\circ}$  (25 $\mu$ g/0.5ml) elicits robust immune response of 97.7%, with four-fold seroconversion across all age groups beyond 6 months of age.
- » Offers high avidity (especially IgG having high bactericidal activity) that persists up to 5 years across all age groups, according to the available data.
- » Co-administration of Typbar TCV® with the MMR vaccine exhibits no serological interference with excellent safety and compatibility.
- » Showed 87.1% of efficacy in a human challenge study at Oxford University.
- » Offers a flexible dose of vaccination along with good safety and immunogenicity, in line with WHO Technical Report Series.