Vaccine Product Profiles for Gavi-supported TCVs

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This resource is part of Gavi's Vaccine Product Profiles (VPPs) for WHO PQ vaccines

- This resource is complementary to Gavi's Detailed Product Profiles (DPPs) for WHO prequalified vaccines: https://www.gavi.org/our-alliance/market-shaping/product-information-vaccines-cold-chain-equipment
- The primary objective of the Detailed Product Profiles (DPPs) is to provide countries with easy access to up-to-date and comprehensive information on Gavi-supported vaccines. The VPPs include additional information on vaccine presentations, pricing, indicative wastage rates, manufacturers, cold chain volume and handling, which are characteristics that need to be assessed by countries to select the most optimal product when multiple choices for Gavi support are available (e.g. rotavirus, HPV, PCV).
- For TCV, the two available products are equivalent. Therefore, countries do not need to make a choice between the products when applying for TCV support. This VPP provides information on the two TCVs available through Gavi support which may be useful to country teams in planning TCV introduction and/or campaigns.
- Information contained in the DPPs comes from a variety of sources including the Gavi Secretariat, WHO PQ vaccine webpages, WHO position papers and UNICEF's product menu for vaccines supplied by UNICEF for Gavi-supported programmes.
- Additional resources relevant for assessing vaccines and presentations:
  - WHO position paper on Typhoid Vaccines: https://apps.who.int/iris/bitstream/handle/10665/272272/WER9313.pdf?ua=1
  - Gavi Support Process and Guidelines: https://www.gavi.org/our-support/guidelines
- Please send comments or questions to: dpp@gavi.org

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Definitions of terms used in the typhoid vaccine product profiles (VPPs)

Price per dose (USD)	Price in USD per dose of the vaccine based on available data. This is an **indicative** price calculated by the Gavi Secretariat to be used by countries for planning purposes. Prices are exclusively for the vaccine and does not include any associated costs including but not limited to freight, cold-chain costs, administrative costs, customs clearance and wastage. When there are multiple suppliers of the same presentation of the vaccine, or when there is a range of prices offered by the same supplier of the vaccine, a weighted average price (WAP) is used.
Vaccine cost per fully immunized person (USD)	The price per dose (USD) is multiplied by the total number of doses required for a completed vaccination according to the WHO recommended vaccine schedules (ref: WHO position papers)
Wastage adjusted vaccine cost per fully immunized person (USD)	Vaccine cost per fully immunized person (USD) is adjusted for vaccine wastage. A wastage rate is calculated for each administered dose to adjust this cost. The wastage rate used in the calculation is indicative and should be replaced by a country specific actual wastage rate or estimate when available. The wastage rate should not be used for planning purposes without considering the coverage rate, as this would overestimate needs.
Cold chain volume per fully immunized person (cm^3)	The cold chain volume per fully immunized person is calculated by multiplying the number of doses required to complete the vaccination according to the WHO recommended vaccine schedules (ref: WHO position papers)
Wastage adjusted cold chain volume per fully immunized person (cm^3)	The cold chain volume per fully immunized person is adjusted to account for vaccine wastage.

Contents of this VPP

- **Product availability through Gavi support**
- **Vaccine composition and clinical profile[1]**
- **Cost**
- **Storage and transport**
- **Programmatic administration considerations**
- **Resources & contact persons**

1. Equivalent to the vaccine performance (characteristics) which include safety, immunogenicity, efficacy/effectiveness

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Typhoid vaccines supported by Gavi

Trade name	Typbar-TCV	TYPHIBEV
Type	**Typhoid conjugate vaccine**	**Typhoid conjugate vaccine**
Manufacturer	Bharat Biotech International Ltd	Biological E Ltd
NRA	Central Drugs Standard Control Organization (CDSCO, India)	Central Drugs Standard Control Organization (CDSCO, India)
Presentation	5 dose/vial, liquid	5 dose/vial, liquid
WHO PQ decision	22.12.2017, PQ File	24.12.2020 PQ File
Availability	Available, with planning	Available, with planning
Photo of vial		

Vaccine composition and clinical profile

Differences in vaccine composition:

- Typbar-TCV: Purified Vi-Capsular Polysaccharide of S. Typhi strain Ty2 conjugated to tetanus toxoid
- TYPHIBEV: Vi polysaccharide is obtained from genetically modified *Citrobacter freundii sensu lato 3056* and conjugated to CRM_{197}

The Comparison Table of WHO prequalified typhoid conjugate vaccines (TCVs) is available here: https://apps.who.int/iris/bitstream/handle/10665/345367/WHO-IVB-2021.04-eng.pdf

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Vaccine cost (direct) at Gavi price

Trade name	Typbar-TCV	TYPHIBEV
Presentation	5 dose/vial, liquid	5 dose/vial, liquid
Price per dose (USD) (2023 weighted average price (WAP))	$1.39	
Doses per fully immunized person	1	1
Vaccine cost per fully immunized person (2023 WAP)	$1.39	
Indicative wastage rate	10%	10%
2023 wastage adjusted vaccine cost per fully immunized person (USD) (WAP)	$1.54	

* Direct vaccine cost includes only the cost of the vaccine and does not include any associated costs including but not limited to freight, cold-chain costs, administrative costs, customs clearance and wastage or cost derived from the vaccine delivery.

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Cost-effectiveness of TCV routine immunization with and without a catch-up campaign at the time of introduction (Ref: WHO position paper)

- Available modelling data indicate that **routine immunization (RI) of infants** with TCV **plus catch-up vaccination of older cohorts** provides additional benefits towards accelerated and sustained decline in typhoid fever incidence, compared with RI alone.[1,2]

- RI plus catch-up was also found to be more cost-effective compared with RI only. It was cost-saving in some of the LMIC settings that were studied in current models. RI alone is also cost-effective (and cost-saving in some settings) compared with no vaccination.

- While these data demonstrate that vaccination with TCV in a variety of strategies and settings is cost-effective or highly cost-effective, the results are highly dependent upon parameters such as incidence of disease and vaccine price. Further cost-effectiveness analyses are warranted and should be part of the country decision-making and planning process to initiate programmatic use of typhoid vaccines.

1. Antillon M et al. Cost-effectiveness analysis of typhoid conjugate vaccines in five endemic low- and middle-income settings. Vaccine. 2017;35:3506–3514. 71
2. Lo NC et al. Comparison of strategies and incidence thresholds for Vi conjugate vaccines against typhoid fever: A cost- effectiveness modeling study. J Infect Dis. 2018;doi:10.1093/infdis/jix598.

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Storage and Transport

Trade name	Typbar-TCV	TYPHIBEV
Shelf-life	36 months at 2-8°C	24 months at 2-8°C
Cold chain volume per dose	2.8cm^3	2.9cm^3
Secondary packaging	Carton of 36 vials (180 doses) Dimensions: 11 x 11 x 4.5 cm Gross weight: ~0.36 KG Net weight: ~0.10 KG Tracing: GS1 compliance	Carton of 48 vials (240 doses) Dimension: 14.5 x 10.5 x 4.5 cm Gross weight: ~0.41 KG Net weight: ~0.37 KG Tracing: GS1 compliance
Tertiary packaging	Box of 32 cartons of 36 vials (1152 vials/ 5760 doses) Dimensions: 66 x 53 x 43 cm Gross weight: ~30 KG Net weight: ~11.5 KG	Box of 32 cartons of 48 vials (1536 vials/ 7680 doses) Dimensions: 66 x 53 x 43 cm Gross weight: ~30.0 KG Net weight: ~13.0 KG
Vaccine vial monitor type	VVM 30	
Handling of open vials	WHO recommends that opened vials of this vaccine may be kept for use in subsequent immunization sessions up to a maximum of 28 days provided the conditions outlined in the WHO Policy Statement “Multi-Dose Vial Policy” are met AND the vaccine was not used under CTC.	WHO recommends that opened vials of this vaccine may be kept for use in subsequent immunization sessions up to a maximum of 28 days provided the conditions outlined in the WHO Policy Statement “Multi-Dose Vial Policy” are met.

Programmatic administration considerations

Trade name	Typbar-TCV	TYPHIBEV
Presentation	5 dose/vial, liquid	5 dose/vial, liquid
Dose quantity	Each vial contains 2.5ml (0.5ml/dose)	Each vial contains 2.5ml (0.5ml/dose)
Administration	Intramuscular (IM) with 0.5mL AD syringe	Intramuscular (IM) with 0.5mL AD syringe
Preparation steps	1	1
Preservative	Phenoxyethanol	Phenoxyethanol
Need for dose measurement in preparation	Yes	Yes

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Key references

- **WHO Vaccine Prequalification information :** https://extranet.who.int/gavi/PQ_Web/Default.aspx?nav=2
- **WHO materials:** https://www.who.int/immunization/diseases/typhoid/en/
- **Gavi Detailed Product Profiles (direct link):** https://www.gavi.org/library/gavi-documents/supply-procurement/detailed-product-profiles/

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Key contacts for questions

Area of expertise	Agency	Person to contact, role, email
Vaccine clinical profile	WHO	• Your Country's officer • Adwoa Demsa Bentsi-Enchill, bentsienchilla@who.int • Jenny Walldorf, walldorfj@who.int
Vaccine wastage rates, WHO wastage rates calculator	WHO	• Souleymane Kone, kones@who.int
Availability, Shipment, Prices	UNICEF SD	• Your Country's officer • Oluwaseun Ayanniyi, oayanniyi@unicef.org • David Kiambi Mutuerandu, dkmutuerandu@unicef.org
Eligibility, Application guidance	Gavi Secretariat	• Your Country's Senior Country Manager • Allyson Russell, TCV Programme Manager, arussell@gavi.org

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