

September 2019

Frequently Asked Questions (FAQs) on Typhoid Conjugate Vaccine (TCV) support

1. What is typhoid fever?

Typhoid fever is a bacterial infection caused by *Salmonella enterica* Typhi. The bacteria multiply in the intestinal tract and can spread to the bloodstream. Typhoid is generally spread by food and water contaminated by faeces. Symptoms include prolonged fever, nausea and constipation. Around 10% of infections can have more serious complications such as intestinal perforation, intestinal haemorrhage and sometimes death.

Given the non-specific presentation, clinical diagnosis of typhoid fever can be challenging due to potential confusion with other common febrile illnesses. In most settings, confirmation of the diagnosis relies on isolation of S. Typhi by blood culture. The sensitivity of a single blood culture is approximately 60% and is affected by the volume of blood obtained for culture. Although treatable through the use of appropriate antibiotics, there is an increasing number of infections that are resistant to traditional antibiotics.

More data on typhoid can be found here: http://www.who.int/mediacentre/factsheets/typhoid/en/

1. What is the WHO Position on typhoid conjugate vaccine (TCV)?

WHO recommends a single dose of TCV in children from 6 months and in adults up to 45 years in endemic regions. WHO also encourages routine programmatic administration of TCV at the same time as other vaccines, at 9 months or in the second year of life. TCV is preferred at all ages in view of its improved immunological properties, use in younger children and longer duration of protection. TCV should be prioritized in countries with high burden of disease or antimicrobial resistance. All typhoid vaccination programmes should be implemented in the context of other efforts to control the disease, including health education, water, sanitation and hygiene (WASH) improvements, and training of health professionals in diagnosis and treatment.

The WHO position paper on typhoid vaccines can be found here: http://apps.who.int/iris/bitstream/handle/10665/272272/WER9313.pdf?ua=1

2. What Gavi support is offered for typhoid fever?

Gavi's Board approved the opening of a funding window for TCVs in November 2017, subject to the vaccine receiving WHO pre-qualification (PQ). On December 22, 2017 the first licensed TCV received WHO PQ.

Gavi provides support to countries for the introduction of TCV into the routine immunisation schedule. This includes vaccines and associated supplies (i.e. injection safety devices).

• Co-financing is required for TCV delivered via routine; and



• A one-time vaccine introduction grant (VIG) to facilitate the integration of the vaccine into the routine programme is also provided.

Gavi also provides support to countries for targeted and tailored catch-up immunisation as appropriate to the country context by providing TCV for a one-time, single dose catch-up vaccination administered to children from 9 months up to 15 years of age.

- Gavi fully finances TCV costs delivered in one-time catch up immunisation; and
- Financial support to cover the operational costs to facilitate the timely and effective delivery of vaccines to the target population is also provided.

See sections 5 – 5.3 in the <u>Application Guidelines</u> for more details.

3. What is the best vaccination strategy?

Countries should use epidemiological data to determine the best vaccination strategy as well as consider other factors such as cost, sustainability, and operational feasibility. The Gavi Alliance is ready to assist countries with choosing the best vaccination strategy, please contact your Gavi Senior Country Manager (SCM) for more information.

4. Our country does not have epidemiological data for typhoid fever, can we still apply?

Yes. It is possible to also use data from modelling or studies. See sections 5 - 5.3 the <u>Application Guidelines</u> for more details regarding guidance on data sources to support application.

5. Our country does not yet have TCV in the comprehensive multi-year plan (cMYP), can we still apply for Gavi support?

Yes. To ensure alignment with other EPI activities, it is important that the introduction of TCV is reflected in the country's cMYP. If not included in the cMYP at the time of application, the introduction of TCV must be reflected in the new/updated cMYP as part of the annual vaccine support renewal process. Guidelines on reporting on and renewal of Gavi support can be found here:

http://www.gavi.org/support/process/apply/report-renew/

6. What is the 2020 application process to request Gavi support for TCV?

All information and resources about this year's application process can be found on Gavi's website: <u>http://www.gavi.org/support/process/apply/vaccine/</u>

The first country application for typhoid conjugate vaccines was received in 2018 with introduction planned for late-2019.



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The 2020 application submission and review timeline for TCV support is summarized below.

2020 Application Rounds	Round 1	Round 2	Round 3
Deadline for application submission	Late January	Early May	Early September
Application review dates (Independent Review Committee)	Mid March	Early Jule	Late October / Early November

For detail on specific dates and submission deadlines please visit Gavi's website: <u>https://www.gavi.org/support/process/apply/</u>

7. How much will TCV cost?

The price of a 5-dose vial of TCV will be \$1.50 per dose for Gavi countries.

8. Are there risks that there will not be enough supply? How will this affect introduction timing?

With only one current WHO pre-qualified vaccine, Gavi anticipates that supply may not meet demand in Gavi supported countries in first 1-2 years of support. Gavi will work closely with its partners to manage the supply and demand balance, which has been successfully done for other markets. In addition, there is a healthy pipeline of additional TCVs that are in late-stage clinical development