
TB VACCINE ACCELERATOR COUNCIL

PROGRESS UPDATE *May–October 2024*

ABOUT THIS UPDATE

The update charts progress achieved by the tuberculosis (TB) Vaccine Accelerator Council and its Secretariat between May and October 2024.

Information presented here is drawn from the 2024 WHO Global TB Report, the activities of the Secretariat, and the Council members. The Update specifically highlights progress on implementing the following recommendations made by the Council to the Secretariat at its second meeting in May 2024:

- To convene a finance and access summit in 2025 and present a set of options that help countries gain timely, reliable access to safe, effective, and affordably priced new TB vaccines.
- To conduct in-country workshops focused on sharing information about the TB vaccine pipeline, discussing national product preferences and deployment plans, and exploring future strategies for vaccine access, financing, and distribution.
- To establish working groups to accelerate progress towards the Council's mission, with a focus on advancing key priorities such as vaccine development, financing, access, health system preparedness, and community engagement.

The Update is structured as follows:

1. **Status overview**
 - Current status of the global TB epidemic
 - Overview of the TB vaccine pipeline
2. **Establishment of the Council's working groups**
 - Key developments and objectives of the working groups
3. **Progress on the planned TB vaccine access and financing summit**
 - Updates on preparations for the summit
4. **National workshop update**
 - Progress in conducting in-country workshops
5. **Ongoing activities and next Steps**
 - Other ongoing initiatives by the Council and its Secretariat
 - Next steps



1. Status overview

STATE OF THE GLOBAL TB EPIDEMIC

TB, a preventable and curable communicable disease, is one of the leading causes of death from an infectious agent worldwide. From 2000 to 2023, TB treatment and antiretroviral therapy for TB-HIV co-infection saved 79 million lives. However, the COVID-19 pandemic, along with inequitable health services, conflicts, climate change, and natural disasters, has significantly hindered progress against TB. In 2023, an estimated 10.8 million people worldwide fell ill with TB, with 55% of cases among men, 33% among women, and 12% in children under 15. This represents a slight increase from 2022, mainly due to population growth. TB-related deaths globally decreased to 1.25 million in 2023—1.09 million among HIV-negative individuals and 161,000 among those with HIV. This decline continues the positive trend seen in 2022, following two years of increases during the worst of the COVID-19 pandemic in 2020 and 2021. Geographically, most people who developed TB in 2023 were in the WHO regions of Africa (24%), South-East Asia (45%), and the Western Pacific (17%), with smaller proportions in the Eastern Mediterranean (8.6%), the Americas (3.2%) and Europe (2.1%). Among all incident cases of TB in 2023, 6.1% were among people living with HIV. The proportion of people with a new episode of TB who were coinfecting with HIV was highest in countries in the WHO African Region, exceeding 50% in parts of southern Africa. Europe had the highest percentage of individuals with TB who developed rifampicin-resistant or multidrug-resistant TB.

THE PIPELINE OF NEW TB VACCINES

As of August 2024, there were 15 vaccine candidates in clinical development: four in Phase I, five in Phase II and six in Phase III. While some candidates are tested across multiple phases for various populations, the pipeline highlights only the most advanced phase. The pipeline includes candidates to prevent TB infection and TB disease, and candidates to help improve the outcomes of treatment for TB disease. A renewed and coordinated commitment to basic discovery research, preclinical studies and clinical trials remains essential to expand the number of candidates in the pipeline.

Phase I	Phase IIa	Phase IIb	Phase III
BNT164a1 ^b BNT164b1 ^b BioNtech SE	ChAdOx185A- MVA85A ^{c,j} University of Oxford	DAR-901 booster ^{e,g} Dartmouth, St. Louis University	GamTBvac ^d Ministry of Health, Russian Federation
TB/FLU-05E ^c RIBSP	ID93 + GLA-SE(QTP101) ^d Quratis ,U.S. NIH/NIAID	RUTI ^e Archive1 Farma, S.L	MIP/Immuvac ^{f,i} ICMR, Cadila Pharmaceuticals
H107e/CAF [®] 10b ^d SSI	AEC/BC02 ^d Anhui Zhifei Longcom		M72/AS01 ^{e,d,g} GSK, Gates MRI
			MTBVAC ^{f,i} Biofabri, University of Zaragoza, IAVI, TBVI
			VPM1002 ^{f,h,g} SIIPL, VPM
			BCG vaccination to prevent infection (TIPI) ^f HJF
^b Messenger RNA (mRNA). ^c Viral vector. ^d Protein/adjuvant. ^e Mycobacterial – whole cell or extract.		^f Mycobacterial – live. ^g Includes adolescents (aged 10–19 years). ^h Includes infants (aged <12 months). ⁱ Includes children (aged <10 years).	

2. Establishment of the Council's working groups

In May 2024, Members of the Council requested the WHO Secretariat to establish working groups to accelerate the achievement of goals aligned to its mission. Four working groups will be established in a phased approach: vaccine research, and innovation; product development, policy & manufacturing; finance & access; and country readiness, advocacy, & community partnership.

The four working groups of the Council



Vaccine research & development

Examples of WG Scope: Advance research into natural history of TB, correlates of protection, new antigens, novel vaccine platforms, assay development, and vaccine delivery modalities



Product development, policy, & manufacturing

Examples of WG Scope: Strengthen alignment on clinical trial designs, streamline regulation and assess manufacturing needs including technology transfer



Financing & access

Examples of WG Scope: Complement existing market analyses, diagnose root causes of potential access problems, and propose market intervention solutions for vaccine distribution



Country readiness, advocacy, and community partnership

Examples of WG Scope: strengthen TB surveillance, develop frameworks for prioritizing high-risk groups, model vaccine impact, align and optimize complementary roles of partners, assess health system readiness, and promote ethical, equitable delivery

HIGHLIGHT: Finance and access working group

The Finance and Access Working Group is being established to propose strategies that promote the timely supply, equitable distribution, and affordable pricing of new TB vaccines, with a particular focus on supporting countries with a high burden of TB. Membership will consist of a diverse range of stakeholders to ensure comprehensive expertise and representation.

The Secretariat aims to launch the working group in 4Q 2024.

3. Towards the 2025 TB vaccine summit

In May 2024, Members of the Council requested the WHO Secretariat to convene an access and financing summit in 2025 and present a set of options that help countries gain timely, reliable access to safe, effective, and affordably priced TB vaccines.

Why: Although high demand for a TB vaccine is anticipated, production capacity challenges could emerge unless demand forecasting and supply chain management are optimized. Additionally, there is a risk of supply bottlenecks, as the production of some vaccine candidates may rely on a single primary supplier. With TB predominantly affecting low- and middle-income countries and having limited market potential in high-income regions, a strategic approach to market shaping is crucial. To address these challenges, global and regional partners, manufacturers, countries, and international agencies must take concerted action to correct market imbalances, foster the development of a robust TB vaccine market, and facilitate timely access.

When: Fourth quarter of 2025 (tbc). WHO is currently exploring various options to identify the most suitable platform for the summit, one that will facilitate meaningful policy dialogue, political and strategic support.

Technical Preparation: The Finance and Access Working Group (see update no. 2) will assist in the technical preparations for the summit.

Outcomes: The launch of a TB vaccine access incentive framework, with options to enhance new TB vaccine availability, affordability, and equitable access.

4. Country workshops

In May 2024, the Council supported plans to conduct in-country workshops focused on sharing information about the TB vaccine pipeline, discussing national product preferences and plans, and exploring future strategies for vaccine deployment, access, and financing.

In partnership with Indonesia's Ministry of Health, WHO [convened](#) the first workshop of this kind 8-9 November 2024 in Bali, Indonesia ahead of the Union World Conference on Lung Health to discuss anticipated use cases, programmatic requirements, potential demand, and strategies for TB vaccine procurement, financing, and access.

5. Ongoing activities and next steps

- **GAVI:** [On 7 June 2024](#), Gavi's Board approved the Vaccine Alliance's strategy for the five-year period running from 2026 to 2030, which will include future vaccine programmes and learning agendas for TB.
- **The WHO Secretariat** officially announced plans to organize the TB vaccine finance and access summit, along with the establishment of relevant working groups, during the 7th Global Forum on TB Vaccines held from October 8-10 in Brazil. Strategic and technical preparations are being made in collaboration with partners to form these working groups using a phased approach.

Next steps

The next quarterly update will be made available in the first quarter of 2025.

If you have any questions in the meantime, please feel free to reach out to TBvaccines@who.int.