

The urgent need for new TB vaccines

The G20 nations are home to over half of the world's TB burden and many of the world's leading research institutions and funding bodies. The G20 has a critical role to play in developing the new TB vaccines and other tools required to End TB.

We urgently need new TB vaccines to end TB

TB is the leading cause of death from an infectious disease in much of the world. Amid already constrained financial support for essential TB services and rising levels of drug-resistance, **1.3 million people died** from TB disease in 2022 and **10.6 million people fell ill** with TB.ⁱ Existing tools for preventing TB are woefully inadequate. In contrast to the unprecedented collaboration in the development of COVID-19 vaccines, there is only one available TB vaccine – the century old Bacille Calmette Guérin (BCG). While BCG offers important but incomplete protection against the most severe forms of TB in infants and young children, it is mostly ineffective in adolescents and adults, who are most at risk of developing and spreading TB.

We need multiple new TB vaccines that work across all age groups, particularly among adults and adolescents, to meet the WHO 2030 End TB goals.ⁱⁱ Universally accessible TB vaccines would fight antimicrobial resistance (AMR), advance health equity, avert millions in household catastrophic costs, improve affected countries' macroeconomic prospects, and advance pandemic preparedness and response (PPR) infrastructure.

New TB vaccines are possible in the next five years

The urgency of the need is matched by the promise of the science. The pipeline of candidates has never been stronger, with at least five vaccines in phase III efficacy trials and work underway to develop next-generation vaccines based on mRNA and other promising platforms.ⁱⁱⁱ **New TB vaccines could be available this decade** – with some ready for licensure within the next five years, by 2028 – **but only if Member States substantially increase adequate, predictable, and sustainable financing for TB vaccine R&D.**

The time to invest in new TB vaccines is now

At the 2018 United Nations High-Level Meeting on TB (TBHLM), Member States pledged to invest US\$2 billion annually in TB R&D over five years. By 2022, less than 37% of the target had been invested – for vaccines, this was less than 20% against an annual target of \$613 million.^{iv} At the 2023 TBHLM, Member States pledged

to deliver new TB vaccines 'preferably' within 5 years and to invest US\$5 billion annually for TB R&D by 2027 of which **\$1.25 billion is needed for TB vaccines**, as outlined in the Global Plan to End TB 2023-2030.^v Yet, funding for TB vaccines has never exceeded \$145 million per year. Reaching this new, more ambitious figure will require a more than eight-fold increase in financing for TB vaccines over current levels. **World leaders must urgently fulfill their commitments to end TB by 2030 by investing their fair share to support a fully funded and resourced TB vaccine pipeline, so that new TB vaccines are available as early as 2028.**

The cost of inaction wildly surpasses the cost of action

TB vaccines are predicted to be highly cost-effective in nearly all high TB burden countries and cost-saving from a societal perspective.^{vi} **Every \$1 invested in the delivery of a new TB vaccine that is 50% effective in preventing disease among adolescents and adults will return \$7 to the global economy over 25 years.**^{vii} In the same period, **up to 8.5 million lives can be saved and up to 76 million cases of TB disease prevented**, averting up to 42 million courses of treatment and reducing the pressure on the global AMR crisis. And the global market for new TB vaccines is huge, with demand forecasts of over 5 billion doses for adolescents and adults.

Existing multilateral mechanisms exclude TB vaccine R&D

The Global Fund is the largest international donor to TB activities, but supports implementation of existing tools, not R&D to develop new tools, like vaccines. Similarly, GAVI leads global efforts to scale-up immunization programs in low- and lower-middle-income countries but does not invest in product development. Conversely, mechanisms like CEPI that focus on vaccine R&D do not prioritize TB. CEPI's 2022–2026 strategy, in line with their investments to date, remains directed toward viral pathogens, not yet TB. **We need innovative funding mechanisms for TB vaccine R&D, ones based on a partnership of funders that bring together different governments and other interested parties in support of an accelerated agenda for TB vaccine R&D.**^{ix}

Invest in TB vaccines to invest in pandemic preparedness

Preventing future pandemics requires tackling the most serious pandemic threats today. TB stands alongside HIV/AIDS, malaria, viral hepatitis, and AMR as deserving concerted attention within any new PPR initiative or international instrument. Moreover, the world needs flexible, adaptable, and sustainable global health R&D funding, capacity, and infrastructure for a successful pandemic response. Investing in TB R&D can build local and global research capacities across the research continuum, driving efficiency in every stage of product development, **while addressing the burden of TB and ensuring the world has the infrastructure to address future threats.**^x

New TB vaccines are key to tackle AMR

Drug-resistant TB (DR-TB) is a leading cause of death due to AMR. Multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB are both on the rise. Of the over 400,000 people estimated to fall sick with drug-resistant TB in 2022, less than 176,000 accessed treatment.^{xi} Moreover, treating DR-TB is many times more expensive than treating drug-susceptible TB. It has been estimated that new TB vaccines could avert over a third of deaths attributable to bacterial AMR.^{xii} Yet, TB has been left out of many AMR initiatives – a missed opportunity to address the heart of the challenge. **New TB vaccines are likely to be equally effective against drug-resistant and drug sensitive TB and reduce the need for antibiotics.**

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The TB Vaccine Advocacy Roadmap (TB Vax ARM) represents a global coalition of TB stakeholders, including TB survivors, civil society organizations, and non-profits, invested in TB vaccine advocacy and research.

Learn more at www.newtbvaccines.org/take-action