TB VAX INFO HUB

TAG Treatment Action Group

Seven Reasons Why The World Needs New TB Vaccines

Advocacy Conversation Starters and Key Messages

We are closer than ever before to having the necessary tools to end tuberculosis (TB), one of the oldest — and still the deadliest — infectious diseases. Every year 1.3 million people lose their lives to TB and over 10 million people fall sick with the disease.[1]

TB keeps young people from school, takes parents from families, and can affect people of any age, from precious newborns to cherished elders. The challenging road to diagnosing TB, and the long and arduous courses of multi-drug therapy required to cure the disease, mean that even those fortunate enough to access care must defer their dreams for months — or even years.

The costs of these deferred dreams compound. Individual TB stories add up to serious societal and economic costs. TB can bankrupt families who are often straddling the poverty line. It is estimated to rob the global economy of $2 trillion per year, or around 1.3% of global GDP.

The world needs new TB vaccines. Without them, the epidemic will not end.

The only existing vaccine against TB, known as Bacille Calmette-Guérin (BCG), was introduced in 1921. BCG is one of the most widely administered vaccines in human history — and it's still used today. Given "as soon as possible after birth," BCG shields infants from some of the most serious forms of TB.

But BCG does not protect adolescents and adults against pulmonary TB disease, which attacks the lungs. Pulmonary TB among young people and adults drives the epidemic forward. Inadequate prevention tools are partly why TB remains the world's leading infectious disease killer year after year.

WITH NEW VACCINES, WE CAN ACHIEVE THE DREAM OF A TB-FREE FUTURE.

Scientific progress has given us a historic window of opportunity to make this dream a reality. Multiple TB vaccine candidates are in late-stage clinical trials testing their safety and efficacy. Results from some of these studies could be available as early as 2028. If shown to be safe and effective, these could become the first new vaccines approved against TB in over 100 years.

That means one or more new TB vaccines could be available in the next 3–5 years.

The world has waited decades, but if science delivers, we won't have to wait much longer. The approval of new vaccines against TB would be a historic scientific triumph, but the journey to eliminating TB would not end with research and development. Innovation must be matched with access so that new vaccines reach people who need their protection. That requires acting now, ahead of clinical trial results. Governments, funders, vaccine developers, global agencies, civil society and communities affected by TB must come together to ensure:

- **READINESS — the right financing and policies are in place to deliver new TB vaccines rapidly and at scale.**
- **RESILIENCE — health systems are fortified to ensure access and uptake by those most at risk.**
- **EQUITY — everyone who needs new TB vaccines can benefit from their protection without delay.**

It's the job of advocates to make sure governments and other duty bearers act. We also need to prepare communities for new TB vaccines by sharing information, answering questions, and getting ahead of misinformation.

The simplest place to begin our advocacy is by starting conversations about TB vaccines. These seven key messages serve as **advocacy conversation starters** to help you engage government decision makers and community leaders. Each message comes with "quick facts," or proof points you can share to back up the message with evidence.

[1] The facts and figures cited here come from the World Health Organization *Global TB Report* and a 2026 study: Wang et al. The global economic burden of tuberculosis: regional disparities and implications. Open Forum Infect Dis. 2026;13(1):ofag014.

1

Conversation Starter

We need preventive vaccines for adolescents and adults to achieve a world free of TB.

Vaccines are central to every major infectious disease elimination effort across the world. The story of TB will be no different.

To end the epidemic, we need to interrupt transmission. TB transmission occurs when people who are infected with *Mycobacterium tuberculosis* develop TB disease in the lungs (pulmonary TB) and cough, speak, sing, or simply breathe. TB can be transmitted asymptomatically, meaning people with TB don't need to be sick enough to report symptoms like cough for the disease to spread.

Simply put, when people share the same air, the TB germ can spread.

Vaccines that keep people safe from pulmonary TB offer one of the best ways of stopping transmission. If people don't get sick, TB won't have the chance to spread.

The BCG vaccine protects infants and young children against severe forms of the disease like TB meningitis (which affects the brain) and miliary TB (which is spread throughout the body). BCG is given to newborns after birth and will remain an essential part of infant immunization for years to come. But BCG has a major limitation: it doesn't shield adolescents and adults from pulmonary TB. Pulmonary TB among these age groups is the primary driver of TB transmission, illness, and deaths.

For this reason, researchers have focused on developing new vaccines that can prevent TB disease in adolescents and adults. The WHO has stated that "the prevention of pulmonary TB disease in adolescents and adults is the priority strategic target in TB vaccine development."

1 Conversation Starter

We need preventive vaccines for adolescents and adults to achieve a world free of TB.

QUICK FACTS:

- The only existing vaccine against TB, BCG, protects infants but does not prevent pulmonary TB among adolescents and adults.
- There are no licensed TB vaccines for adolescents and adults, who account for 90% of pulmonary TB and are the primary source of TB transmission.
- A new TB vaccine that is 50% effective in preventing disease in adolescents and adults, and with protection that lasts for 10 years, can avert between 37 and 75 million cases of TB and save 8.5 million lives over the next 25 years.[2]
- Vaccines that protect adolescents and adults will also reduce TB rates among children, since most children get TB from the adults around them.

WANT TO LEARN MORE?

The WHO has outlined key characteristics and evidence supporting the use of new TB vaccines for adults and adolescents in two documents:

1. Preferred Product Characteristics for New Tuberculosis Vaccines
2. WHO Evidence Considerations for Vaccine Policy Development for Tuberculosis Vaccines Intended for Adults and Adolescents

[2] The facts and figures cited here draw from *An Investment Case for New TB Vaccines*, published by WHO.

2

Conversation Starter

New TB vaccines won't be a silver bullet, they will add to and strengthen existing prevention tools.

Safe and effective vaccines for adolescents and adults will be required to end the TB epidemic, but they won't be able to do the job alone.

There are many ways to prevent TB, and vaccines are just one important piece of keeping people safe from tuberculosis. New TB vaccines will complement — not replace — other prevention tools, like TB preventive treatment and good nutrition.

TB prevention can be *biomedical* (using tools like vaccines or preventive treatment), *environmental* (practicing infection control in high-transmission settings like prisons, mines, or healthcare clinics), or *social* (ensuring dignified living conditions by ending hunger, providing housing, or alleviating poverty).

In other words, preventing TB is a **biosocial** endeavor that draws power from implementing different interventions across multiple levels.

Even with new TB vaccines, some people will continue to develop TB and will need to be diagnosed and treated. Vaccines therefore won't end the need to develop better diagnostic tests and treatment regimens. **Once new TB vaccines are available, governments will need to decide how to introduce them alongside existing tools.**

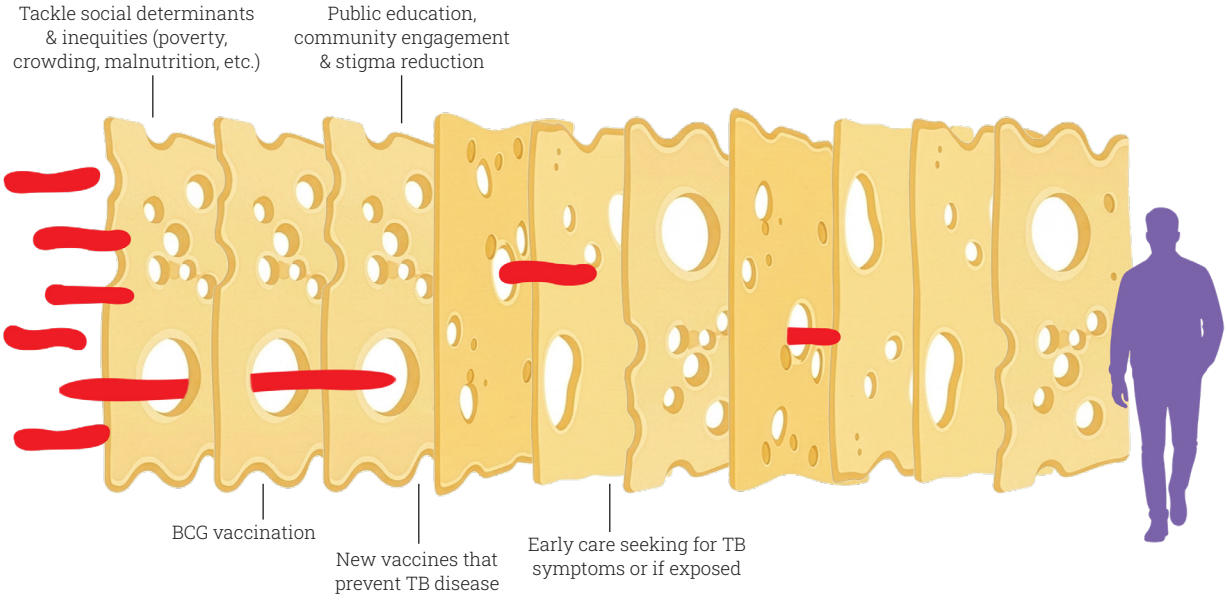
One way to understand the multilayered approach to TB prevention is the "Swiss Cheese Model for Ending TB," adapted by leading TB researchers Dr. Madhukar Pai and Dr. Jennifer Furin from an idea first proposed by Dr. Ian Mackay to understand COVID-19 prevention. Prevention is the outcome of layering interventions, each of which has gaps just as a swiss cheese is riddled with holes. The chances of the TB germ exploiting any one gap are minimized when different tools are brought together as part of a comprehensive prevention strategy.

2 Conversation Starter

New TB vaccines won't be a silver bullet, they will add to and strengthen existing prevention tools.

MULTIPLE LAYERS OF PREVENTION IMPROVE SUCCESS

SOCIETAL → PERSONAL → PERSON-CENTRIC HEALTHCARE SYSTEM



Treatment saves lives by curing people with TB. Preventive treatment can protect those exposed to TB but not yet sick from the disease. Early detection can identify people who need treatment, and psychosocial support helps people finish their treatment and achieve cure. BCG is there too to protect infants.

But some layers are missing. One of the biggest gaps will only be filled by new vaccines that protect adolescents and adults from TB disease.

QUICK FACTS:

- Preventive treatment (TPT) consists of taking short courses of TB drugs and protects people who are already infected with TB from getting sick with TB disease. In the future, some of these drugs may be available as long-acting formulations administered via a single injection.
- Malnutrition is a leading risk factor for TB, responsible for an estimated one million TB cases each year. A study in India found that giving a monthly food supplement to the household contacts of people with TB cut their risk of developing TB within the next two years by 52%.
- One study compared the epidemiological and budgetary impacts of different TB interventions and found that things that prevented transmission — namely, vaccines that prevent disease and community-wide for early diagnosis — can have substantial epidemiological impact while being cost effective.

WANT TO LEARN MORE?

The following resources are good places to start if you want to learn about TB prevention, nutrition, and other interventions to prevent TB.

1. An Activist's Guide to Rifapentine – TB Preventive Treatment: 3HP and 1 HP (Treatment Action Group).
2. Fuelling the Fight Against the Spread of TB: Nutrition Is the Missing Ingredient (RESULTS UK).
3. A modelling study "Global impact and cost-effectiveness of tuberculosis interventions" by Katherine Horton and colleagues, published in Nature Health.

3

Conversation Starter

A promising late-stage pipeline has brought us within reach of the first new TB vaccines in more than 100 years.

Thanks to dedicated research and development efforts, scientists have created a promising "pipeline" of vaccine candidates at various stages of clinical testing. The pipeline contains different types of vaccines, including:

- ***subunit vaccines*** that combine specific proteins from the TB organism, selected to trigger protective immunity, paired with adjuvants, which are substances that boost the body's immune response to the proteins.
- ***live-attenuated vaccines*** that use a weakened version of the TB germ or closely related organisms to trigger protective immunity without causing disease.
- ***mRNA vaccines*** that deliver a piece of genetic material (mRNA, or messenger RNA) that instructs the body to make proteins from the disease-causing pathogen to trigger protective immunity against it.

Candidates in the pipeline are being tested first and foremost to demonstrate safety and efficacy. Other important considerations include feasibility (minimal number of doses, temperature stability), affordability (low cost-of-goods, sustainable supply chain requirements), and acceptability (minimal side effects or injection site pain).

Candidates early in the pipeline are undergoing phase I and smaller phase II trials to generate data on their safety and immunogenicity (ability to trigger a desired immune response). Those in later stages of the pipeline have advanced to larger phase II and phase III trials testing their efficacy (whether they prevent TB disease) with the goal of obtaining licensure.

Once late-stage trials conclude and results are published, regulators will carefully evaluate the data to decide whether to license and approve the vaccines.

3 Conversation Starter

A promising late-stage pipeline has brought us within reach of the first new TB vaccines in more than 100 years.

AT A GLANCE: TWO ADVANCED CANDIDATES IN THE PIPELINE

KEY FEATURE	M72/AS01E	MTBVAC
VACCINE PLATFORM	Protein + adjuvant	Live-attenuated
DOSING	2 doses	1 dose
SPONSOR AND MAJOR PARTNERS	Gates MRI, Serum Institute of India, GSK	Biofabri, Bharat Biotech, FAP (Brazil)
CURRENT STAGE	Phase III	Phase III (infants) Phase IIb (adolescents/adults)
PHASE III TRIAL PLANS	Underway among 20,000 people in Indonesia, Kenya, South Africa, Malawi, and Zambia	Starting soon among ~25,000 people in India
MAIN TARGET POPULATION	Adolescents & adults with TB infection	Adolescents & adults with TB infection
HIV POPULATION	Safety & immunogenicity data within smaller cohort	Separate safety studies
2028 MILESTONE	Phase III results expected	Interim results from Phase IIb/III trials could be available
2029 MILESTONE	Regulatory submissions could begin if results are positive	Submissions for conditional regulatory approval could be sought on positive interim results; full approval will await phase III trial data

3 Conversation Starter

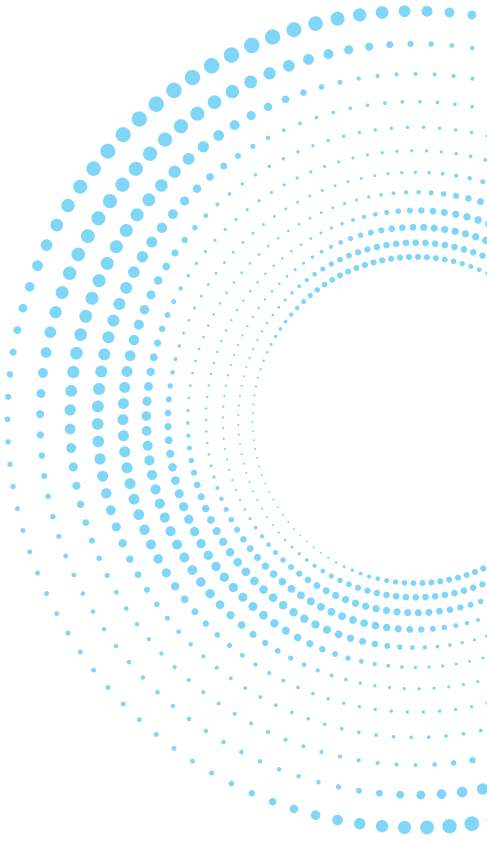
A promising late-stage pipeline has brought us within reach of the first new TB vaccines in more than 100 years.

QUICK FACTS:

- As of October 2026, the TB vaccine pipeline has 14 candidates, including 4 in late-stage efficacy trials.
- TB vaccine research is a global endeavor: over 20 countries are hosting clinical trials of TB vaccines that combined are enrolling over 100,000 participants.
- In 2025, the world spent $230 million on TB vaccine research and development; most of this funding comes from governments and philanthropies.
- If results from late-stage trials are positive, M72/AS01E and MTBVAC could earn regulatory approval and become the first TB vaccines to be introduced in more than a century. They could be followed by other vaccines in the pipeline, including an mRNA TB vaccine candidate supported by BioNTech (BNT164).

WANT TO LEARN MORE?

Explore the pipeline for new TB vaccines on the website of the Working Group on New TB Vaccines and read TAG's TB Vaccines Pipeline Report.



4

Conversation Starter

New TB vaccines will lower TB costs, advancing equity and contributing to economic growth.

The economic benefits of new TB vaccines are many. Nearly half of affected households face catastrophic expenditures in which the costs of diagnosing and treating TB exceed 20% of their annual household income.[3] For these families, a new vaccine is not just a public health intervention, but a financial lifeboat.

Adolescent and adult vaccines that meet the WHO Preferred Product Characteristics will be cost effective in all high-TB-burden countries and in a majority of low- and middle-income countries from both health system and societal perspectives.

There are some upfront costs governments will pay to purchase vaccines and fund their delivery through routine immunization services and vaccination campaigns. But the returns far outweigh these costs in the form of health and economic benefits.

By preventing illness, vaccines will avert the costs associated with diagnosing and treating TB — for individuals, families, and health systems. This will save the direct costs of diagnosis and treatment and generate even more far reaching benefits when people are healthy enough to work, study, take care of their families, and contribute to their communities without TB getting in the way.

The quick facts below break down the economic benefits of new TB vaccines using concepts like *return on investment* and *cost-effectiveness* and draw from a strong evidence base of economic and mathematical modelling.

For communities affected by TB, these benefits would represent more than modeled estimates: they would come as tangible resources and real opportunities. For governments, these benefits create a compelling case for investing in new TB vaccines as an obvious "best buy."

4 Conversation Starter

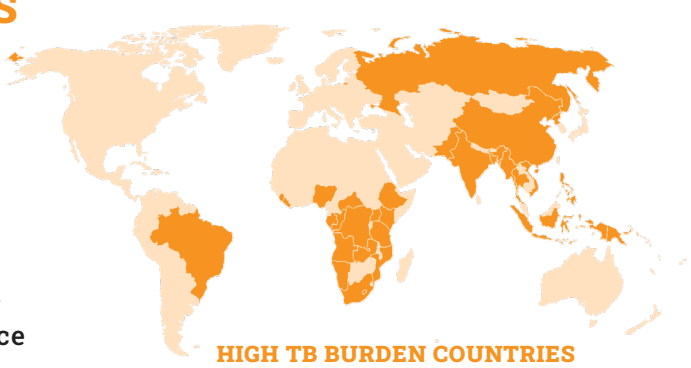
New TB vaccines will lower TB costs, advancing equity and contributing to economic growth.

NEW TB VACCINES CAN ADVANCE HEALTH EQUITY

AMONG COUNTRIES

$283–$474 BILLION

in **health and economic benefits** by 2050, with greater benefits in LMICs with elevated TB incidence

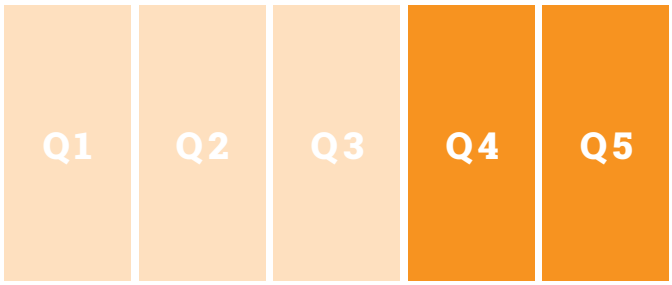


HIGH TB BURDEN COUNTRIES

AMONG INDIVIDUALS

56%

total TB cases prevented would be among individuals in the **lowest two income quintiles**



AMONG FAMILIES

23 MILLION

families will be protected from catastrophic costs, with **66% of averted catastrophic costs** among families in the **poorest 40% of the population**



NEARLY 1/2 of families affected by TB **suffer catastrophic costs**

4 Conversation Starter

New TB vaccines will lower TB costs, advancing equity and contributing to economic growth.

QUICK FACTS:

- **Return on investment:** The WHO *Investment Case for New Tuberculosis Vaccines* found that every $1 invested in adolescent and adult vaccines will return $7 to the economy in the form of health and economic benefits over 25 years.
- **Rost-effectiveness:** Adolescent and adult TB vaccines will be **cost-effective** in all high-TB-burden countries from both a health system and societal perspective. New TB vaccines will be **cost-saving** in a majority of low- and middle-income countries from a societal perspective, which accounts for individual non-medical costs and productivity losses.
- **Ambition dividends:** Compared with business-as-usual approaches, ambitious scale-up plans that accelerate vaccine introduction produce greater health benefits and make new TB vaccines *more* cost effective. This suggests countries can reap an "ambition dividend" if they act quickly and make new vaccines available without delay.
- **Health equity:** Evidence suggests that new TB vaccines will improve health equity because more of the expected health and economic benefits will accrue to poorer individuals/families and countries with greater burdens of TB. Over time, this could reduce income-based disparities in TB outcomes.

WANT TO LEARN MORE?

The data cited here on the health and economic benefits of new TB vaccines come from the following two papers by Allison Portnoy, Rebecca Clark, and other collaborators:

1. Portnoy A, Clark R, et al. The cost and cost-effectiveness of novel tuberculosis vaccines in low- and middle-income countries: a modeling study. PLoS Med. 2023;20(1):e1004155.
2. Portnoy A, Clark R, et al. The potential impact of novel tuberculosis vaccines on health equity and financial protection in low-income and middle-income countries. BMJ Glob Health. 2023. 8(7):e012466.

[3] The figures cited here draw from The Global TB Report 2025, published by WHO.

5

Conversation Starter

New TB vaccines will cut antibiotic use and help stop drug resistance, minimizing pressure on fragile health systems.

New TB vaccines could help reverse the rise of drug-resistant TB, which is a leading cause of death from antimicrobial resistance.

Antimicrobial resistance (AMR) occurs when bacteria, viruses, or parasites stop responding to medicines. As a result, infections become more difficult (and costly) to treat. The United Nations has described AMR as "one of the most urgent global health threats" and has recognized drug-resistant TB as one of the most challenging contributors to the AMR problem.

Drug-resistant TB claims 150,000 lives every year and is found in every country in the world. In 2024, nearly 400,000 people developed drug-resistant TB, and rates are rising in some regions, including the Americas and Southeast Asia. Drug-resistance levels are much higher in the WHO European region, where 23% of new cases are drug-resistant, compared with the global average of 3.2%.

Treatment of drug-resistant TB has improved markedly over the past decade thanks to the availability of shorter, safer treatment regimens built around new drugs. But better tools for preventing drug-resistance are urgently needed.

New TB vaccines would offer a powerful tool against AMR. Because the mechanisms of vaccine protection will be different than those that confer drug resistance, new TB vaccines are likely to be equally effective against both drug-sensitive and drug-resistant TB. By protecting people from developing TB disease, vaccines will reduce the need for antibiotics, which will help limit the development of resistance and its onward transmission.

Prompt diagnosis and effective treatment are necessary but insufficient for addressing DR-TB; bolstering prevention by adding safe and effective vaccines into the mix would make a major difference.

5 Conversation Starter

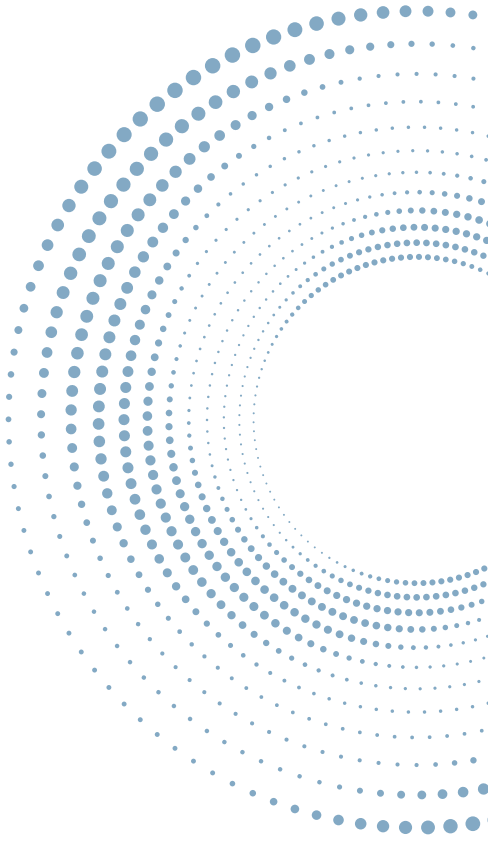
New TB vaccines will cut antibiotic use and help stop drug resistance, minimizing pressure on fragile health systems.

QUICK FACTS:

- New TB vaccines could avert over one-third of deaths attributable to bacterial AMR.
- Adolescent and adult TB vaccines could prevent the need for 22–42 million antibiotic treatments over the next 25 years, and save up to $3.2 billion in treatment costs associated with drug-resistant TB diagnosis and treatment.
- The WHO has issued an urgent call for new vaccines to tackle AMR, designating the development of more effective TB vaccines with the highest priority level in its analysis of bacterial vaccines in development.

WANT TO LEARN MORE?

The quick facts above come from the WHO Investment Case for New TB Vaccines and a concise summary of the TB and AMR overlap published by the TB Vax ARM coalition: *New TB Vaccines Needed to Tackle AMR*.



6

Conversation Starter

Countries bearing the highest TB burden are leading the call for new vaccines, and preparing for their arrival.

Some of the strongest voices calling for new TB vaccines come from government leaders from high-TB-burden countries. These voices signal that there is strong political will to develop and deploy new TB vaccines and suggest that demand will be high once vaccines are licensed and approved.

Ministers of health from countries across the world have come together to form the TB Vaccine Accelerator Council, a high-level forum hosted by the WHO "to facilitate the development, testing, authorization, and use of new TB vaccines." The Accelerator Council is chaired by ministers of health from Indonesia and Brazil and unites representatives of governments, funders, development banks, global agencies, and civil society and TB-affected communities to prepare for this historic opportunity. The Accelerator Council has created working groups to address different dimensions of preparedness including clinical and policy issues; finance and access; and country readiness, advocacy, and community partnerships.

Countries are demonstrating commitment to TB vaccines in multiple ways. Some countries are hosting clinical trials in partnership with lead developers. Countries including Brazil, Kenya, Indonesia, Malawi, South Africa, and Zambia have held planning workshops, supported by the Accelerator Council, bringing together national regulatory authorities, national TB and immunization programs, civil society, and other stakeholders to begin preparing for new vaccines.

In South Africa, a Novel TB Vaccine Preparedness Consortium has formed to lead preparatory activities, and the government is working with stakeholders to create a national implementation roadmap. In Indonesia, the government has included new TB vaccines in its 2025–2029 national immunization strategy, and the national regulatory authority has confirmed the eligibility of TB vaccines for accelerated review.

6 Conversation Starter

Countries bearing the highest TB burden are leading the call for new vaccines, and preparing for their arrival.

QUICK FACTS:

- Strategic dialogues and in-depth consultations with countries representing over half of the world's TB burden and likely to be early adopters of new TB vaccines indicate that political support exists — but detailed planning and decision making await key evidence from clinical trials and confirmation of product availability and outside financing.
- A global demand forecast developed by Gavi for the Finance and Access Working Group (a part of the Accelerator Council) estimates demand for 1 billion vaccine regimens between 2030 and 2040. This would require up to 120 million regimens annually in the first five years and 90 million annually thereafter.
- There is no earmarked funding available for TB vaccine procurement, which could cost between US$5–8 billion between 2030 and 2040 (not including costs associated with vaccine delivery). Raising domestic and global funding remains an urgent priority.

WANT TO LEARN MORE?

Read the 2025 report of the Finance and Access Working Group of the TB Vaccine Accelerator *Catalysing Solutions for Equitable Global Access and Sustainable Financing for Novel Tuberculosis Vaccines for Adults and Adolescents*. The report contains global supply and demand projections for new TB vaccines and proposes six solutions to accelerate equitable access and sustainable financing.

[3] The figures cited here draw from The Global TB Report 2025, published by WHO.

7

Conversation Starter

Coming together around sustainable financing, clear regulatory pathways, and strong health systems strengthening will be essential to ensure a TB vaccine reaches those who need it most.

It's up to us. Realizing the full health and economic benefits of future licensed TB vaccines will depend on the preparations we make together now — globally, nationally, and locally.

Bold planning today can set the stage for demand to scale to tens of millions of vaccines annually. More cautious approaches will curtail demand to the low millions, leaving most people at risk of TB unprotected.

Successful early planning requires coming together to work on financing, regulatory, policy, and health systems delivery strategies. If we wait until after late-stage trials are completed to start thinking about these issues, communities affected by TB will wait years to receive new TB vaccines. Each year of delay has a cost — new cases, lives lost, and families driven into poverty.

The goal is to create the right conditions for the scientific breakthrough of a new TB vaccine to be matched by the social triumph of equitable access.

To accomplish this, many actors will need to drop business-as-usual approaches. Developers will need to become more transparent about pricing, licensing, and supply plans. Funders will need to commit financing before the outcome is certain. Regulators will need to act with speed and collaborate across borders. Governments will need to bring together two health programs used to operating separately — national TB programs and immunization services — and make decisions about vaccine delivery and procurement earlier than is typical when introducing a new tool. And advocates will need to start talking to communities about new TB vaccines before they are available and devise clever ways to stay ahead of vaccine mis/dis-information.

Some countries will be eligible to receive outside financial support from Gavi and/or Global Fund. Others will need to finance new TB vaccines primarily through domestic resources.

7 Conversation Starter

Coming together around sustainable financing, clear regulatory pathways, and strong health systems strengthening will be essential to ensure a TB vaccine reaches those who need it most.

QUICK FACTS:

- Procurement of new TB vaccines for adults and adolescents for all countries globally could cost $5-8 billion between 2030 and 2040.
- Funding needs extend beyond procurement to include vaccine delivery costs, implementation research, and post-licensure evidence generation.
- Political support is growing but no country has allocated domestic funds for a future TB vaccine. Countries need clarity on product attributes, supply availability, pricing, and financing options.

WANT TO LEARN MORE?

The following two publications describe the actions stakeholders should take to prepare for new TB vaccines:

1. Global Framework to Prepare for Country Introduction of New TB Vaccines for Adults and Adolescents (World Health Organization). Provides a framework to guide countries in facilitating the planning, investments, and preparations required to make new adolescent and adult TB vaccines available.
2. Catalyzing Solutions for Equitable Global Access and Sustainable Financing for Novel Tuberculosis Vaccines for Adults and Adolescents (TB Vaccine Accelerator Council Finance and Access Working Group). Projects vaccine supply and demand and identifies six solutions to accelerate access and financing, highlighting the roles of different stakeholders.