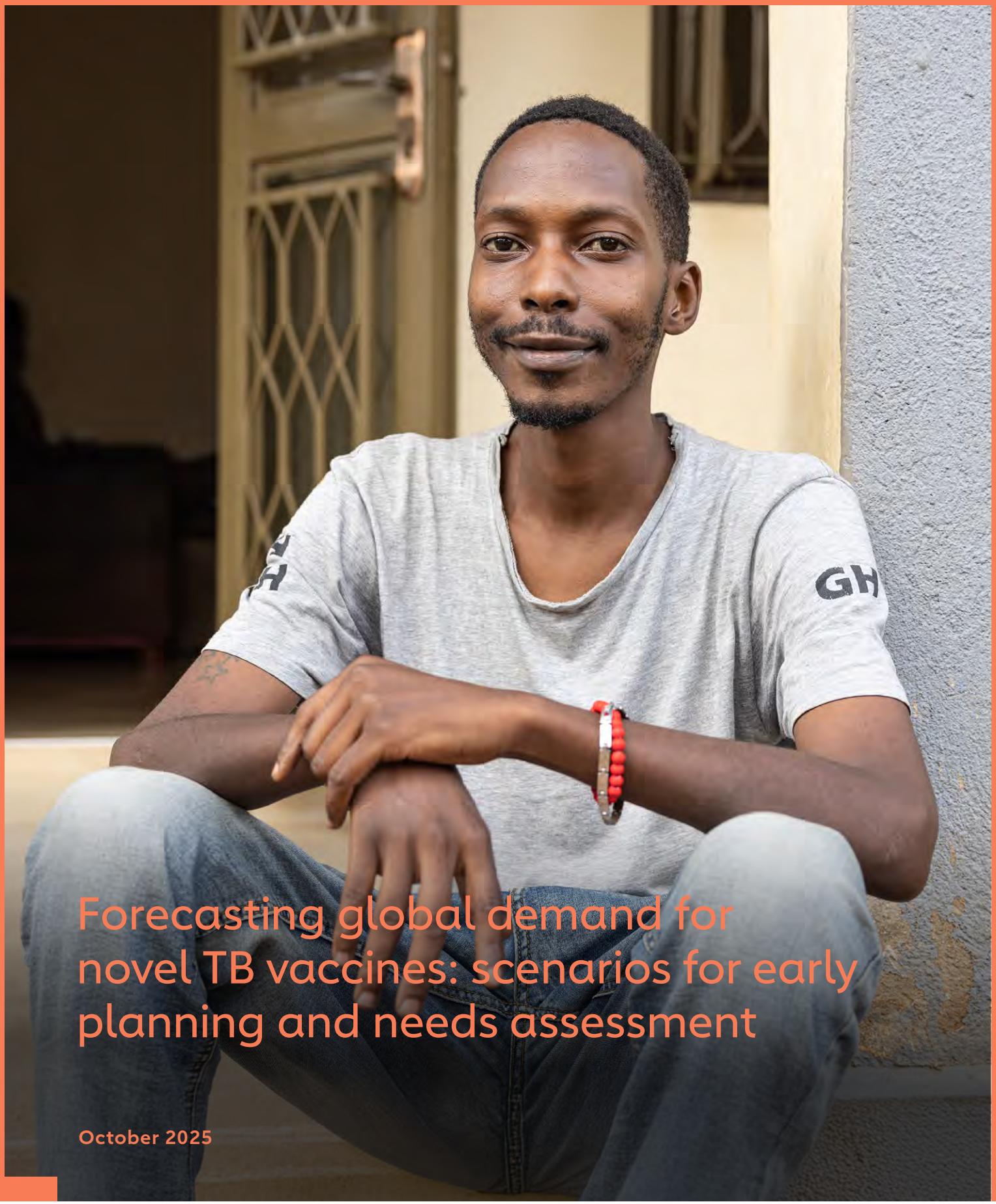

Forecasting global demand for novel TB vaccines: scenarios for early planning and needs assessment

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Gavi The Vaccine Alliance

CLINTON HEALTH ACCESS INITIATIVE

MMGH CONSULTING

Executive summary

Tuberculosis (TB) remains the leading infectious disease worldwide, causing 10.8 million cases and 1.3 million deaths in 2023, with 90% of the burden concentrated in low- and middle-income countries. While current prevention tools are inadequate to effectively eliminate TB, novel TB vaccines for adolescents and adults are currently in advanced clinical trials with early modelling suggesting that such vaccines could significantly reduce TB incidence and mortality.

Following the Gavi Board's 2024 'in principle' approval to support novel TB vaccines to inform early market shaping and planning efforts, Gavi, the Vaccine Alliance (Gavi), Clinton Health Access Initiative, Inc. (CHAI) and MMGH Consulting (MMGH) developed a global, supply-unconstrained demand forecast for 2030–2040, building on the World Health Organization (WHO)'s MI4A methodology and consultations with more than 120 stakeholders across nine high-TB burden countries. The forecast quantifies potential adolescent and adult vaccination needs under four scenarios – maximum public health need, high, medium and low – reflecting varying levels of programmatic ambition, as a function of potential financing, acceptability of vaccines, and programmatic feasibility and readiness.

The WHO TB Vaccine Accelerator Finance and Access Working Group reached consensus that the high-demand scenario best balances health impact and feasibility. This scenario also aligns with country ambition expressed during consultations, assuming product characteristics align with the WHO Preferred Product Characteristics (PPC), and the availability of funding and affordable prices. This approach combines routine immunisation of adolescents and select high-risk groups with targeted catch-up vaccination of adolescents and adults living in high-burden areas, aiming for a rapid reduction in TB incidence. Under this scenario, demand is projected to peak at about 120 million courses in the first five years of introduction and stabilise around 90 million annually by 2040.

As a next step, Gavi will develop and publish an early market shaping roadmap which will further evaluate the demand scenarios and state which scenario(s) will inform strategic market shaping priorities and planned activities to enable sustained access to future TB vaccines.

Cover image: Elieza Kwizera, a plumber in Uganda who was infected with TB as an infant, says, "TB … is a very difficult disease to have. It took long to be diagnosed, and it left me with some minor spinal complications."
Credit: Gavi/2023/Esther Ruth Mbabazi

Context

Tuberculosis (TB) is the world's leading cause of death from an infectious agent, with 10.8 million cases and 1.3 million deaths in 2023, predominantly in low- and middle-income countries.[1] The World Health Organization (WHO) has identified 49 countries as high-burden, which represent approximately 90% of the global TB burden.[2] Eight of these countries (Bangladesh, China, Democratic Republic of the Congo, India, Indonesia, Nigeria, Pakistan and Philippines) represent more than two thirds of new TB cases.[1]

As part of WHO's End TB Strategy, countries plan to reduce TB incidence by 90% and TB deaths by 95% by 2035 compared to 2015 rates.[3] However, since 2015, incidence has only reduced by 8%, and deaths by 23%.[4] These shortcomings are in part due to insufficient prevention tools: the Bacille Calmette-Guérin (BCG) vaccine is administered to children soon after birth and protects them against TB, especially severe forms like TB meningitis. However, the BCG vaccine has shown waning effectiveness over time, leaving adolescents and adults with little to no protection against TB.[5] TB preventive treatment requires costly screening to confirm latent TB infection and rule out active TB disease, followed by long treatment regimens with adherence issues, and is usually focused only on high-risk groups, all of which limit its effectiveness.[6] Given these limitations, and the central role that adolescents and adults with active pulmonary TB disease play in spreading *Mycobacterium tuberculosis* infection, the WHO Preferred Product Characteristics (PPC) for New Tuberculosis Vaccines indicates that the priority target for development are vaccines indicated for the prevention of pulmonary TB disease in adolescents and adults.[7]

If successfully developed, novel TB vaccines targeting adolescents and adults will present an important addition to the preventive measures against TB. While novel TB vaccine candidates are still in clinical trials, with the most advanced candidates in phase three and expected to reach licensure earliest around 2030,[8] modelling as part of the 2022 WHO Investment Case for New Tuberculosis Vaccines indicated that even a moderately effective TB vaccine targeting adolescents and adults (i.e. 50% efficacy) could significantly reduce TB incidence and mortality, cumulatively averting up to 76 million cases and 8.5 million deaths by 2050.[9] The investment case further noted that a new TB vaccine for adolescents and adults would have a greater impact than one for infants.

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[1] WHO Global Tuberculosis Report (2024)
[2] WHO Global Lists of High-Burden Countries for TB, HIV-associated TB and Drug-resistant TB (2021)
[3] WHO The END TB Strategy (2015)
[4] WHO Implementing the End TB Strategy (2022)
[5] Hatherill et al. (2022): Infant BCG vaccination is beneficial, but not sufficient
[6] WHO Consolidated Guidelines on Tuberculosis: Module 1: Prevention - Tuberculosis Preventive Treatment (2024)
[7] WHO Preferred Product Characteristics for New Tuberculosis Vaccines (2022)
[8] Stop TB Partnership: TB Vaccine Pipeline (2024)
[9] WHO: An investment case for new tuberculosis vaccines (2022)

Following the Gavi Board's 2024 'in principle' approval to support novel TB vaccines,[10] Gavi performed a global demand and supply analysis to inform early market shaping efforts to prepare for the introduction of novel TB vaccines targeting adolescents and adults, and to ensure an optimised launch. As part of these efforts, Gavi, the Vaccine Alliance (Gavi), Clinton Health Access Initiative, Inc. (CHAI) and MMGH Consulting (MMGH) developed a demand forecast for novel TB vaccines to understand country programmatic ambition and potential introduction scenarios; inform resulting supply and financing needs; and contribute to the early alignment and coordination of the global health ecosystem, including implementing countries, donors, TB vaccine developers and future suppliers. The demand forecast has also been used to inform the work of the WHO TB Vaccine Accelerator Finance and Access Working Group that is co-led by WHO, the Gavi Secretariat and the Government of South Africa.[11]

This demand forecast builds on previous efforts, including Gavi's Vaccine Investment Strategy (VIS) 2024 forecast. Its assumptions and scenarios are informed by more extensive country and expert consultations, as well as key product-specific insights.[12] Much remains uncertain about the eventual characteristics of the vaccines that are in development (e.g. number of doses, efficacy, indication, policy recommendations, product price), which will influence their eventual adoption and use. This demand forecast has therefore been developed as a supply-unconstrained, product-agnostic, early needs assessment to inform anticipatory market shaping activities and introduction planning, and not as a procurement forecast.

The demand forecast quantifies the number of novel TB vaccine courses for adolescents and adults across all WHO Member States and covers the 2030–2040 period. As new information on the vaccine candidates or country introduction plans becomes available, this forecast will be updated on an iterative basis.

Methodology

The TB vaccine demand forecast is based on WHO's MI4A (Market Information for Access to Vaccines) methodology, which has been endorsed by the WHO Technical Advisory Group on Market Access for Vaccines and has been used to develop global demand forecasts for 13 antigens to date.[13] The methodology has been adapted to account for uncertainties surrounding novel TB vaccine candidates. For this purpose, experts on TB and immunisation from a range of global and regional organisations, including Gavi, Gates Foundation, London

[10] Gavi Vaccine Investment Strategy (2024)
[11] The WHO TB Vaccine Accelerator Finance and Access Working Group aims to ensure timely, equitable and affordable access to new TB vaccines for countries with high public health needs and includes country representatives from high-burden countries, global experts, civil society organisations, as well as finance and development partners.
[12] Product-specific insights (e.g. estimated dates of licensure) were incorporated into the assumptions where relevant.
[13] WHO Market Information for Access to Vaccines (last accessed on 28 July 2025)

School of Hygiene & Tropical Medicine, UNICEF, University of Cape Town, WHO and the TB Vaccine Accelerator Finance and Access Working Group (see Annex A1), as well as country stakeholders in nine high-TB burden countries accounting for 63% of global TB burden (Brazil, China, Democratic Republic of the Congo, India, Indonesia,[14] Nigeria, Pakistan, South Africa,[14] and Viet Nam) were interviewed, and their consolidated inputs used to inform the assumptions and scenarios in this forecast.[15]

Country-level interviews included a broad range of stakeholders to capture a holistic view of each country's ambition for novel TB vaccination. Depending on the country context, participants included representatives from national and subnational TB programmes, immunisation programmes, other ministry of health divisions, regulatory agencies, National Immunisation Technical Advisory Groups, development partners, researchers, national procurement agencies, national treasuries and civil society organisations. In total, more than 120 stakeholders were consulted across the nine high-burden countries through individual interviews and workshops.

The demand forecast has been developed using a standard population-based forecasting approach that aims to quantify the number of novel TB vaccine courses (rather than doses, given the product-agnostic nature of this demand forecast) required for a complete primary vaccination series (i.e. no booster doses assumed) and to achieve different levels of programmatic ambition over the 2030–2040 period, represented through different scenarios. The estimate is based on the size of the target population in each scenario; the assumed delivery strategy to reach each target population; the attainable coverage of the vaccine; country adoption timelines; vaccine wastage; and, where relevant, buffer. Country archetypes are used to make assumptions about novel TB vaccine adoption in different epidemiological settings. In the following paragraphs, the key elements of the demand forecasting methodology are described in more detail.

Target population and delivery strategy

In the absence of a global policy recommendation on target populations for novel TB vaccines, WHO's Evidence Considerations for Vaccine Policy (ECVP)[16] are used to define the scope of potential target populations for vaccination.[17] Using the ECVP as a starting point, we identified the target populations that are both identifiable (i.e. no screening required) and reachable by the health system (i.e. existing touchpoints with population) through consultations with global experts and country stakeholders. These groups were subsequently included in the forecast.

[14] Stakeholder consultations were conducted in collaboration with the London School of Hygiene & Tropical Medicine (LSHTM).
[15] Full list of stakeholders interviewed for this demand forecast can be found in the Annex A1 of this report.
[16] WHO Evidence Considerations for Vaccine Policy Development for Tuberculosis Vaccines Intended for Adults and Adolescents (2024)
[17] Travellers from low-burden countries to high-/mid-burden countries added as additional target population.

As such, the demand forecast includes three categories of target populations:

- Adolescents (15 years old), reached via routine immunisation (RI), to provide population immunity in the longer term.
- Older adolescents and adults (16–44 years old), reached via large-scale catch-up vaccination either nationwide or in high-risk areas, to ensure rapid population-wide coverage.
- High-risk groups (HRG) most susceptible to TB, reached via catch-up vaccination and routine immunisation, to ensure rapid and continued protection. High-risk groups include people living with HIV (PLHIV), household contacts of TB patients (HHC), healthcare workers (HCW), miners, prisoners, people diagnosed with diabetes, migrants and travellers.

For the nine high-burden countries consulted, the top three HRGs are prioritised based on interview insights; for all remaining countries, HRGs are prioritsed based on global datasets (e.g. relative risk factors in WHO ScreenTB dataset[18]).

Coverage

Country-specific coverage estimates for each target population and delivery strategy are based on analogues from existing vaccines or other health programmes (e.g. HPV vaccine coverage rates as a proxy for adolescents; more details in annex A2 and A3). For routine immunisation, the forecast assumes that countries will take three years to reach this coverage estimate, modelled with a linear ramp-up. This uptake assumption is consistent with assumptions taken in other vaccine demand forecasts. For catch-up vaccination, the forecast assumes that countries will conduct these in a phased approach over three to six years, depending on their population size, due to the potential scale of these vaccination activities (i.e. vaccination of a significant number of age cohorts).

Introduction year

The number of introductions per year assumed in the forecast is based on historical adoption patterns for new vaccines and takes into account the current context of crowded immunisation schedules, country financing constraints, and need for balance with other new vaccines and health interventions. Each country's introduction year is determined through a combination of relative TB incidence, financial status and past vaccine adoption behaviour – with adjustments made based on country-specific inputs. The earliest year of introduction is assumed to be 2030.

[18] WHO ScreenTB

Country archetypes

Input from technical experts led to proposed division into three country archetypes based on differences in TB epidemiology. The target populations described in the previous sections are varied across country archetypes to reflect different programmatic goals in different epidemiological contexts:

- **high-burden countries:** 49 countries on WHO's high-TB burden list,[19] accounting for 67% of the world's population and 91% of TB incidence
- **mid-burden countries:** 49 countries with TB incidence above 50 cases per 100,000 population, accounting for 9% of the world's population and 6% of TB incidence
- **low-burden countries:** 98 countries with TB incidence below 50 cases per 100,000 population, accounting for 24% of the world's population and 3% of TB incidence

Demand scenarios

Given the stage of TB vaccine development, key product attributes (e.g. number of doses, efficacy, price) and global policy recommendations remain uncertain. To address these uncertainties and reflect different levels of ambition influenced by potential financial constraints, product characteristics, programmatic feasibility considerations, and the acceptability of vaccines as shared by country stakeholders, the forecast includes four demand scenarios, reflecting a range of introduction approaches that emerged in the consultations.

The maximum public health need scenario represents the **upper bound of demand**, assuming all adolescents and adults for whom the vaccine is likely to be indicated are vaccinated in high- and mid-burden countries through catch-up vaccination and routine immunisation. Broad catch-up vaccination is expected to bring the highest and fastest public health impact in line with the goal of TB elimination.[20]

The high-demand scenario reflects the goal of **accelerating impact on the TB burden** by vaccinating all eligible adolescents and adults in high-burden geographic areas and high-risk groups through catch-up vaccination, achieving fast reduction in TB cases and deaths, while routinely vaccinating adolescents to provide population immunity in the longer term.

[19] WHO Global Lists of High-Burden Countries for TB, HIV-associated TB and Drug-resistant TB (2021). Thirty countries on each list; of this, 20 countries with highest estimated number of incident TB cases/incident TB cases among people living with HIV/estimated number of incident MDR/RR-TB cases, plus the top 10 countries with highest estimated TB/TB-HIV/MDR-TB incidence rates not in the top 20 (threshold: >10,000 estimated incident TB cases per year/>1,000 estimated incident TB/HIV cases per year/>1,000 estimated incident MDR/RR-TB cases per year)

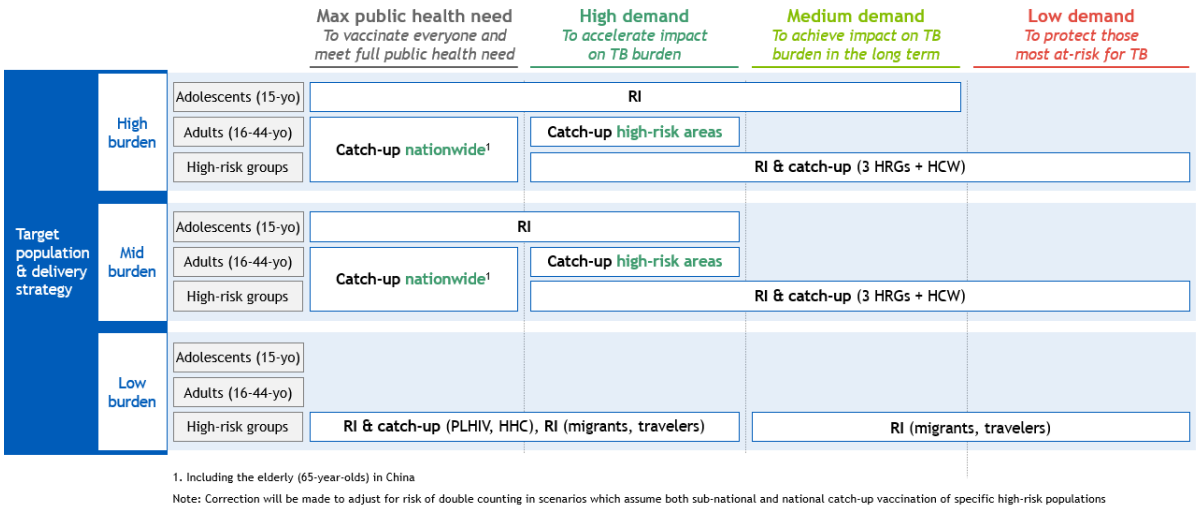
[20] Portnoy et al. (2023): The cost and cost-effectiveness of novel tuberculosis vaccines in low- and middle-income countries: A modeling study

The medium-demand scenario reflects a **longer-term approach to reducing TB burden**. This scenario assumes high-risk groups most susceptible to TB are vaccinated first through catch-up vaccination, while routinely vaccinating adolescents provides population immunity in the longer term.

The low-demand scenario represents the **lower bound of demand** in which only high-risk groups most susceptible to TB are vaccinated through catch-up and routine vaccination.

These scenarios were adapted per country archetype to reflect different levels of programmatic ambition in different epidemiological contexts (Figure 1). High-burden countries are assumed to take the most comprehensive approach to vaccination, while low-burden countries are assumed to only vaccinate a subset of potential high-risk groups across all scenarios.

Figure 1: Demand scenarios differentiated by country archetype



Where required, these scenarios have been further adapted based on country-specific inputs for the nine countries interviewed. Further country-specific adaptions could be made in future iterations of the forecast following additional country consultations.

Results

Country consultation insights

The consultations focused on understanding countries' interest in novel TB vaccines, potential target populations and corresponding delivery strategies, as well as introduction timelines. Across countries, several key themes emerge:

Interest: Consultations revealed a strong interest in novel TB vaccines in all countries, with the level of adoption contingent on high efficacy (i.e. preference for vaccine at or above WHO PPC threshold of 50%), safety and affordability. High vaccine prices as well as limited access to domestic or official development assistance (ODA) funding for novel TB vaccines could delay or reduce the scope of country introductions. Countries emphasised the need for local cost-effectiveness analyses compared to other TB interventions to justify investments in novel TB vaccines but also noted the need to consider the long-term sustainability of both global and domestic funding sources for their national immunisation programmes.

Target populations: While almost all countries voiced a preference for a broad population approach aiming to vaccinate all eligible adolescents and adults, several countries outlined more targeted and phased approaches focused on specific high-risk groups, particularly during the early years of an introduction or in case of resource constraints, supply shortages or lower-than-expected vaccine efficacy. In these cases, countries would prioritise health workers; household/close contacts; people living with HIV and diabetics; as well as miners and prisoners – depending on the national context and pending WHO policy recommendations, especially for priority populations like people living with HIV (given the importance of HIV/TB comorbidity in several high-TB-burden countries).

Delivery strategies: All countries stressed their intention to integrate TB vaccine delivery into existing systems where health services are provided, such as schools and care centres for TB, HIV and non-communicable diseases. However, countries acknowledged that large-scale catch-up vaccination would likely be required in case of a broad population roll-out and would likely be phased starting with high-burden areas. Any roll-out would require early and strong advocacy in the general population to counter stigma and minimise vaccine hesitancy.

Introduction timelines: Countries noted different introduction timelines influenced by their respective disease burden, political will and financing availability. Some countries with a domestic manufacturing footprint indicated a preference for locally manufactured vaccines, but most also indicated their willingness to introduce imported novel TB vaccines initially and transition to local products later in order not to delay introduction.

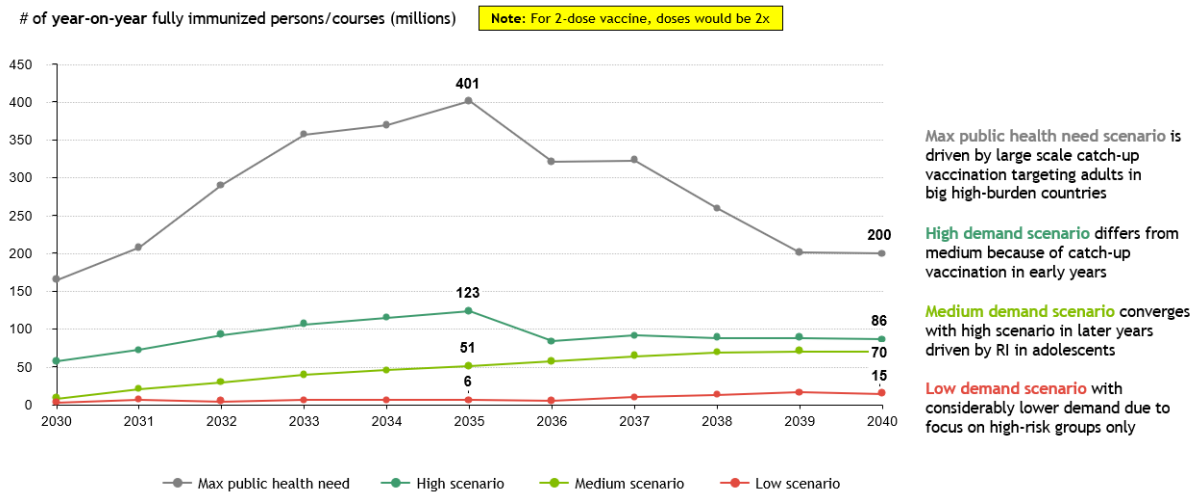
Cross-cutting findings

The projected demand for novel TB vaccines differs significantly between scenarios, given the scope of vaccination assumed under each (Figure 2). It is important to note that the demand is calculated in courses (i.e. for a vaccine with a regimen of two doses, the figures below would double, for a three-dose vaccine would triple, etc.).

Across all four scenarios, the same 52 countries are forecast to introduce novel TB vaccines from 2030 through 2040 based on the introduction year methodology described above; all other countries are modelled to introduce later than 2040. These 52 countries are predominantly high-TB burden countries and account for 74% of the world's population and 95% of global TB incidence. Seven of the countries forecast to introduce are located in the WHO South-East Asia Region (accounting for 26% of the world's population and 45% of global TB incidence), 27 countries are in the WHO African Region (accounting for 14% of the world's population and 23% of global TB incidence) and six countries in the WHO Western Pacific Region (accounting for 21% of the world's population and 17% of global TB incidence). The remaining 12 countries are spread across the WHO Eastern Mediterranean Region, WHO Region of the Americas and WHO European Region.

Of the 52 countries projected to introduce novel TB vaccines from 2030 through 2040, 32 are eligible for external funding through both Gavi and the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund); 14 are eligible for Global Fund funding only; and 6 are not eligible for funding from either organisation. As such, availability of sufficient financing will likely be a key driver for most countries to introduce.

Figure 2: Forecast novel TB vaccine courses, 2030–2040



Maximum public health need scenario

The maximum public health need scenario represents the upper bound of demand, assuming all adolescents and adults for whom the vaccine is likely to be indicated are vaccinated through catch-up vaccination. **Under this scenario, the vaccine volumes to conduct broad catch-up vaccination are estimated to be substantial in the first five to seven years of product availability.** Demand is projected to reach up to ~400 million courses in 2035, driven largely by catch-up vaccination in high-burden countries with large populations (e.g. India, Indonesia, South Africa, Nigeria). India represents around 50% of this demand over the first five years of vaccine introduction. Over time, demand is estimated to stabilise at ~200 million courses annually following the completion of large-scale catch-up vaccination and scale-up of routine immunisation.

Under this scenario, early demand is driven by large-scale catch-up vaccination of the adult population. The share of demand for routine immunisation grows throughout the forecast period as it is scaled among adolescents.

High-demand scenario

Under the high-demand scenario, demand is projected to peak at ~120 million courses in the first five years of vaccine availability, driven by catch-up vaccination in high-risk areas of high-burden countries. Over time, global demand stabilises at around ~90 million courses annually following the completion of catch-up vaccination activities and the scale-up of routine immunisation. Similar to the maximum public health need scenario, India constitutes a large share of overall demand under this scenario – around 60% over the first five years of vaccine introduction.

Early demand under this scenario is driven by large-scale catch-up vaccination of eligible adolescents and adults in high-burden areas and high-risks groups. As catch-up vaccination activities in large countries conclude beyond 2035, routine immunisation comprises most of the demand.

Medium-demand scenario

While the medium-demand scenario is projected to reach only slightly less annual demand (~70 million courses) than the high-demand scenario (~90 million courses) within the first decade of vaccine introduction, **the scenario's uptake curve is flatter due to the focus on adolescent routine immunisation alongside routine and catch-up vaccination of high-risk groups**. India represents around 50% of the forecast demand over the first five years of vaccine introduction in this scenario.

Under this scenario, demand from routine immunisation comprises the vast majority of projected volumes in the forecast period.

Low-demand scenario

Under the low-demand scenario, annual demand is projected as less than 20 million courses due to the sole focus on reaching high-risk groups. In the early years, demand is predominantly driven by catch-up vaccination of these high-risk groups in large high-burden countries (e.g. PLHIV in South Africa). Over time, the share of routine immunisation increases; and beyond 2035, routine immunisation comprises the majority of demand.

Discussion

Throughout the consultations for this demand forecast, countries have expressed strong interest and political will regarding the future use of novel TB vaccines targeting adolescents and adults. However, given the vaccines' current stage of development, a high level of uncertainty related to key product characteristics (e.g. efficacy, number of doses, price) remains, as well as uncertainties around availability of funding, global policy recommendations and programmatic feasibility, which will all influence eventual adoption and use. In response to these uncertainties, this report outlines four potential levels of programmatic ambition regarding target populations for vaccination and the delivery approaches used to reach them, as a function of potential financial constraints, product characteristics, acceptability of vaccines, and programmatic feasibility and readiness.

Under the maximum public health need scenario, demand is projected to peak at ~400 million courses annually within five years of introduction, driven by nationwide catch-up vaccination in adults paired with routine immunisation in adolescents. However, this scenario would require levels of planning, resources and political will similar to those of COVID-19 vaccination. An approach focused on catch-up vaccination of adults in high-risk geographies, and routine immunisation of adolescents and high-risk groups under the high-demand scenario, seems more realistic – and is still likely to accelerate impact towards TB elimination, while resulting in a lower peak demand of ~120 million courses annually within the first five years (before stabilising at ~90 million courses by 2040). Should there be constraints (e.g. financing, supply) that limit programmatic ambition, a more targeted approach focused on achieving long-term impact on TB via routine immunisation of adolescents and high-risk groups under the medium-demand scenario leads to a flatter uptake curve, plateauing at ~70 million doses annually within ten years. Focusing on vaccination of high-risk groups only, for example, due to severe funding constraints or a low relative cost-benefit, is projected to reach less than 20 million courses per year under the low-demand scenario. However, this scenario would fall vastly short of reaching the full potential of novel TB vaccines in terms of TB burden reduction because a focus on high-risk groups only would result in low population-level vaccination coverage. Importantly, across the maximum, high and medium scenarios, India constitutes a large share of overall demand: between 50–60% over the first five years of the forecast.

The WHO TB Vaccine Accelerator Finance and Access Working Group discussed the four demand scenarios and their relative benefits, reaching consensus that the high-demand scenario best balances the ambition to accelerate health impact with implementation feasibility by limiting adult catch-up vaccination to high-risk areas. Adult catch-up vaccination, combined with routine immunisation of adolescents under this

scenario, is likely to accelerate the reduction of TB burden as a greater proportion of the general population is quickly protected.[21] This consensus has thereby established a clear level of global programmatic ambition for novel TB vaccines that can inform the actions needed to deliver the aspired impact on TB burden.

Among the factors influencing whether this programmatic ambition for novel TB vaccines translates into materialised vaccine demand, some cannot be directly influenced at this stage. Specifically, the vaccine efficacy for candidates in late-stage development and their resulting policy recommendations will depend on the outcomes of clinical trials and additional evidence generation activities that are under way. A vaccine with low efficacy and/or a narrow policy recommendation would make the materialisation of the high-demand scenario less likely. However, for other critical factors – including the mobilisation of global and domestic financing to support vaccine procurement and delivery, the predictability of country demand, the manufacturing capacity of vaccines in late-stage development and their respective prices – collaborative efforts can help maximise the availability and impact of novel TB vaccines.

The timely introduction of vaccines at scale will be dependent on the mobilisation of sufficient financing – domestic and/or official development assistance (ODA) – to procure the required vaccine volumes and finance service delivery. In the high-demand scenario, catch-up vaccination accounts for ~50% of demand between 2030–2040; and supporting this scale of vaccination will likely require a significant portion of financing in early years compared to the long-term financing needs of routine immunisation with novel TB vaccines. The high-demand scenario also projects ~90% of novel TB vaccine demand in 34 middle-income countries, 29 of which are eligible for existing ODA mechanisms (i.e. Gavi or Global Fund), while 5 are not eligible for funding support. Different financing approaches may be necessary to support equitable access to novel TB vaccines in these geographies and accelerate TB burden reduction globally.

Predictability of country demand is critical to inform the financing requirements and provide appropriate signals to manufacturers. Country-level cost-effectiveness analyses, for a range of price and efficacy assumptions and comparison of novel TB vaccines with other TB preventive measures, are necessary to inform country introduction plans and the associated budget requirements; and generate an increasingly credible demand signal for manufacturers. In conjunction with this, demand generation activities in collaboration with civil society organisations and local communities will also be important.

[21] Clark et al. (2023): The impact of alternative delivery strategies for novel tuberculosis vaccines in low-income and middle-income countries: a modelling study

The availability of sufficient vaccine supply at affordable prices will be crucial to enable the desired programmatic ambition to be realised under all scenarios. To meet the large volume requirements in the high-demand scenario to support catch-up vaccination that can accelerate TB burden reduction, near-term manufacturer supply planning is required now. In particular, the annual volumes required in the first five years after introduction are substantially higher than the volume levels at which demand is projected to stabilise in the long-term. This peak demand could materialise even earlier and at a higher level, if countries prioritise implementation of a more rapid roll-out of TB vaccines than assumed in this forecast. This kind of early peak in demand could create challenges for manufacturer production capacity investments, which are based on stable, long-term demand estimates. Recognising the complex environment in which novel TB vaccines may be launched – which includes country and donor fiscal constraints, and availability of other high-impact vaccines for introduction (e.g. malaria, RSV, dengue) – the feasibility of different timelines for implementation of catch-up vaccination requires further evaluation to understand implications on reduction of TB burden, financing requirements and potential market shaping activities.

In summary, the demand forecast ranges presented in this report represent an important advancement in how countries' potential approaches to future use of novel TB vaccines are characterised and quantified. For implementing countries, this report provides early insights into the demand implications of including different target populations and delivery strategies in their eventual implementation plans for novel TB vaccines. The outputs of this report can also provide valuable insights for developers and manufacturers, enhancing their understanding of this imminent market and informing supply capacity planning. Further, the report can support governments, multilateral organisations and donors to assess the potential financing requirements; and to initiate early efforts to mobilise the financing needed to meet the WHO TB Vaccine Accelerator Finance and Access Working Group's and countries' stated levels of ambition. As new insights about novel TB vaccines become available, this forecast will be updated to guide coordinated efforts among all stakeholders, as an essential input into strategies for accelerating access to these vaccines.

As a next step, Gavi will develop an early market shaping roadmap for novel TB vaccines in Q4 2025, which will further evaluate the demand scenarios and state which scenario(s) will inform further planning and the associated funding required for a high impact TB vaccine programme. In addition, it will define strategic market shaping priorities and activities, and propose potential roles and interventions in support of an optimised launch of a novel TB vaccine programme. Historically, vaccine market shaping efforts led by Gavi have focused on financing, aggregation of demand, and ensuring affordability and available supply. Given its long-standing role in shaping vaccine markets and the development of innovative financing mechanisms to ensure equitable and sustainable access to affordable vaccines, Gavi is strongly positioned to play a key role in enabling access to novel TB vaccines.

Acknowledgements

Gavi, the Vaccine Alliance (Gavi), Clinton Health Access Initiative, Inc. (CHAI) and MMGH Consulting (MMGH) would like to thank the technical experts and stakeholders across global organisations and nine high-TB burden countries who have provided input for this demand forecast over the course of its development or have contributed to this report.

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Annex

A1. Stakeholders consulted for this demand forecast

Organisations

- Africa Centres for Disease Control and Prevention[22]
- Africa Development Bank[22]
- Asia Development Bank[22]
- European Investment Bank[22]
- Gates Foundation
- Gavi, the Vaccine Alliance[22]
- Global Fund to Fight AIDS, Tuberculosis and Malaria[22]
- Harvard T.H. Chan School of Public Health[22]
- London School of Hygiene & Tropical Medicine[22]
- MedAccess[22]
- PAHO Revolving Fund[22]
- Treatment Action Group[22]
- UNICEF[22]
- University of Cape Town
- World Health Organization[22]
- World Bank Group[22]

Countries

- Brazil
- China
- Democratic Republic of the Congo
- India
- Indonesia[23]
- Nigeria
- Pakistan
- Philippines[22]
- South Africa[23]
- Viet Nam

A2. Coverage analogues for routine immunisation

Target population	Analogue	Rationale for analogue selection
People living with HIV (PLHIV)	Coverage of antiretroviral therapy (ART) [country-specific]	ART coverage reflects the extent to which PLHIV are engaged in healthcare systems
Household contacts	Coverage of TPT among eligible household contacts [country-specific]	Uptake of TPT reflects health system engagement with target population

[22] Member of WHO TB Vaccine Accelerator Finance and Access Working Group
[23] Stakeholder consultations were conducted in collaboration with the London School of Hygiene & Tropical Medicine (LSHTM)

Prisoners	90% vaccination coverage [global value]	Extensive healthcare provision for prisoners mandated in most countries; can assume high vaccination coverage
Miners	90% vaccination coverage [global value]	Extensive healthcare provision for miners mandated in most countries; can assume high vaccination coverage
Healthcare workers	Influenza vaccination coverage in healthcare workers OR COVID-19 vaccination coverage, last dose [country-specific]	Indicator of uptake for a vaccine linked to occupational exposure
People living with diabetes (PLHIV)	Coverage of diabetes treatment [country-specific]	Represents individuals with diagnosed diabetes engaged in healthcare system
Migrants	COVID-19 vaccination coverage, last dose [country-specific]	Close traction of migrants can be assumed for most receiving countries; can assume good vaccine coverage

A3. Coverage analogues for catch-up vaccination

Target population	Analogue	Rationale for analogue selection
People living with HIV	Coverage of ART [country-specific]	ART coverage reflects the extent to which PLHIV are engaged in healthcare systems
Household contacts	Coverage of TPT among eligible household contacts [country-specific]	Uptake of TPT reflects health system engagement with target population
Prisoners	90% vaccination coverage [global value]	Extensive healthcare provision for prisoners mandated in most countries; can assume high vaccination coverage
Miners	90% vaccination coverage [global value]	Extensive healthcare provision for miners mandated in most countries; can assume high vaccination coverage

Healthcare workers	Influenza vaccination coverage in healthcare workers OR COVID-19 vaccination coverage, last dose [country-specific]	Indicator of uptake for a vaccine linked to occupational exposure
People living with diabetes	Coverage of diabetes treatment [country-specific]	Diabetes treatment coverage represents individuals with diagnosed diabetes engaged in healthcare system
Migrants	Median coverage from menA catch-up vaccination campaigns [global value]	Indication of how well a new non-infant vaccine might be received outside standard immunisation programmes