Report on Advancing Policy and Decision-Making for TB Vaccine Introduction in South Africa: A Preparedness Workshop

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ACRONYMS

Acronym	Definition
ART	Antiretroviral Therapy
AVAT	African Vaccine Acquisition Trust
BCG	Bacille Calmette-Guérin (TB vaccine)
CHW	Community Health Worker
EPI	Expanded Programme on Immunization
GAVI	Global Alliance for Vaccines and Immunization
GMP	Good Manufacturing Practice
HIV	Human Immunodeficiency Virus
IGRA	Interferon-Gamma Release Assay
LMIC	Low- and Middle-Income Country
M72/AS01E	Leading TB vaccine candidate
NAGI	National Advisory Group on Immunization
NDOH	National Department of Health
PAVM	Partnership for African Vaccine Manufacturing
PHC	Primary Healthcare
PLHIV	People Living with HIV
SAHPRA	South African Health Products Regulatory Authority
SATVI	South African TB Vaccine Initiative
TB	Tuberculosis
WHO	World Health Organization

EXECUTIVE SUMMARY

South Africa's high tuberculosis (TB) burden, with an incidence rate of 427 per 100,000, more than triple the global average, underscores the urgent need for new tools to combat the disease. The recent South Africa TB Vaccine Preparedness Workshop, convened by the National Department of Health and the World Health Organization brought together government officials, academic researchers, manufacturers, the national regulatory authority, civil society, and global health partners to assess the country's readiness and evidence needs for introducing novel TB vaccines for adolescents and adults, expected as early as 2028–2029. Key insights from the discussions highlight both opportunities and challenges in vaccine adoption but critically, provides guidance for work which remains to be better prepared to rapidly introduce and scale a novel TB vaccine.

Promising vaccine candidates, such as M72/AS01$_E$ (which demonstrated 50% efficacy in a phase 2b trial) and MTBVAC, are advancing through late-stage clinical trials, in which South Africa play a central role. Modelling indicates that a vaccine with 50% efficacy could prevent 1.6 million TB cases and 220,000 deaths in South Africa by 2050 and that a vaccine with even 20% efficacy could be impactful. However, successful rollout faces hurdles, including poorly developed adult and adolescent vaccination platforms, funding constraints, and staffing shortages within the national immunization program. Lessons from COVID-19 vaccination efforts emphasize the need to also address demand generation, vaccine confidence and hesitancy proactively with a need to understand community perspectives and preferences.

Equitable and impactful implementation will require identifying and prioritizing high-risk groups, such as people living with HIV, healthcare workers and adolescents, while ensuring clear communication to avoid potential stigma.

Regulatory preparedness is underway with SAHPRA already engaged in discussions with developers and manufacturers and considering pathways to expedite approvals. The National Advisory Group on Immunisation (NAGI) has already established and convened a TB Vaccine Working Group and have identified evidence gaps to be addressed post-licensure for broad use in key populations. Local manufacturing capabilities, led by BioVac and Afrigen, are expanding and have the potential to support South African and eventually regional supply, but scaling up production will require sustained investment and clarity on the size of the demand. Community partnership and trust-building emerged as critical factors, with recommendations to leverage TB survivors, traditional leaders, and national campaigns to counter misinformation and build vaccine acceptance. Financing remains a challenge, as South Africa, an upper-middle-income country, is ineligible for GAVI support and must secure sustainable domestic and global funding.

Moving forward, South Africa will prioritize immediate action to finalize and disseminate this workshop report while developing a *Roadmap for Accelerated Implementation of Novel TB Vaccines for Adults and Adolescents in South Africa.* This roadmap will guide advocacy at global forums like the November 2025 G20 meeting and to prioritise critical next steps, focusing on aspects such as South Africa-based cost effectiveness analysis for novel vaccine introduction, strengthening adult and adolescent vaccination systems, advancing local manufacturing, conducting health system readiness assessments, generating evidence through implementation studies, and co-creating community engagement strategies. By addressing these priorities, the country can position itself as a global leader in TB vaccine adoption, turning scientific progress into lifesaving public health impact.

INTRODUCTION

Background

South Africa faces a major public health crisis from Tuberculosis (TB), bearing one of the highest global burdens where TB remains a leading cause of death. This impact is disproportionately felt by groups vulnerable to TB disease, including people living with HIV and those in poor, high-density communities. While current TB prevention and management strategies have critical limitations, the development of new vaccines offers a beacon of hope for eliminating TB by 2035. However, the journey from a successful vaccine trial to effective public health impact is fraught with challenge. The research-to-practice gap is often wide, and this is acutely true for populations like adolescents and adults, who bear a high burden of transmission and mortality. This demographic is often more difficult to reach through traditional health campaigns, being mobile, economically active, and often with a low perceived risk of disease. Therefore, there is a need for implementation research on TB vaccines to be conducted now; early preparedness is essential to design the innovative delivery systems, communication strategies, and equitable access plans required for success. It was to directly address this urgent need for cross-disciplinary planning that this workshop was convened

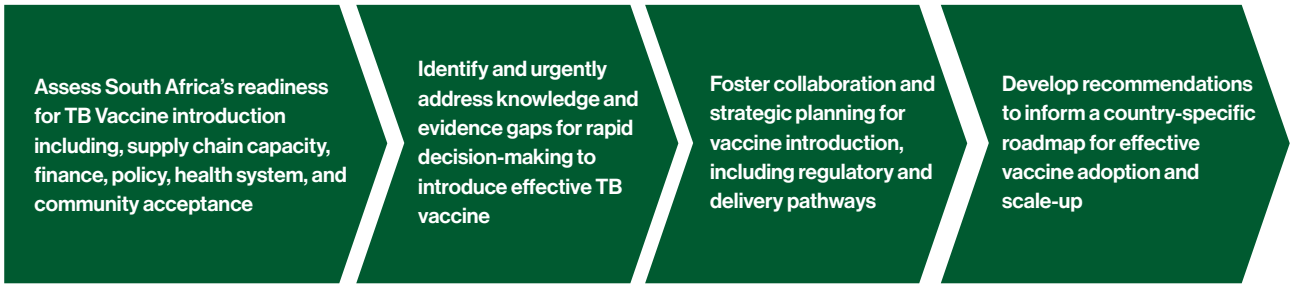
Rationale for the workshop

After decades of novel TB vaccine research and significant candidate attrition, several novel TB candidates are now in Phase III clinical trials, with South Africa playing a central role. This signals a pivotal opportunity to start the conversations about introducing TB vaccines in South Africa. As an early adopter of health innovations and a key player in global TB research, South Africa is uniquely positioned to be one of the countries to lead TB vaccine introduction efforts. The South African National Department of Health (NDoH) in collaboration with the World Health Organisation (WHO), convened the first ever South Africa TB Vaccine Preparedness Workshop in July 2025. This workshop aimed to identify the evidence needed to advance policy and decision making for TB vaccine introduction in South Africa.

Early in April 2025, a steering group, was established to provide critical guidance on workshop objectives, agenda, participant inclusion, speakers/chairs as well as overall tracking of workshop progress.

Workshop goals and alignment with national/global TB elimination strategies

The workshop was designed to accelerate South Africa's path toward TB elimination by addressing critical priorities for country preparedness for TB vaccine introduction. The four key goals were:



These efforts directly support the National TB Programme's Strategic Plan (2023-2028) and align with global targets including:

- The WHO End TB Strategy's 2035 elimination goals
- The UN High-Level Meeting commitments on TB
- The WHO TB Vaccine Accelerator Council

South Africa already has a history of being an early adopter of new TB interventions including Gene Xpert, Urine LAM, Bedaquiline etc. By addressing both immediate operational needs and long-term strategic planning, it is hoped that the workshop outcomes would position South Africa as a leader in the next era of TB prevention through vaccination.

WORKSHOP PLANNING OVERVIEW

The two-day Advancing Policy and Decision-Making for TB Vaccine Introduction in South Africa: A Preparedness Workshop was held in Sandton, Johannesburg, from 23–24 July 2025.

The workshop was jointly organised by WHO, NDoH and coordinated by the Aurum Institute in close collaboration with the steering committee which brought together senior TB and vaccine experts, technical advisors, and patient advocates from national advisory bodies, research institutions, WHO, and civil society. Key members included representatives from the South African NDoH TB Cluster, the National Advisory Group on Immunisation (NAGI), Vaccines for Africa, Africa Health Research Institute (AHRI), the WHO South Africa Office, the South African TB Vaccine Initiative (SATVI), TB Proof, and the WHO African Regional Office (AFRO). The full list of members can be found in Appendix 4.

An attendee list (Appendix 1) was decided upon to ensure diversity across sectors and disciplines, as well as include key individuals and groups who would be responsible for preparedness activities. Representation extended across more than 60 organisations and 85 potential attendees, encompassing government, research, industry, civil society, multilateral agencies, funders, and developers. The selection ensured a balanced mix of policy decision-makers, technical experts, researchers, manufacturers, funders, and community voices, with geographical reach spanning national, provincial, regional, and global perspectives. This diversity created the basis for a comprehensive, multi-sectoral dialogue on TB vaccine preparedness in South Africa.

Government and Public Health Officials were strongly represented, with national leadership including the Minister of Health, the Director General, and the Acting Deputy Director General, alongside multiple directors and managers from the NDoH TB Cluster, Expanded Programme on Immunisation, Health Products Procurement, and Affordable Medicines Directorate. Provincial TB and EPI managers from six provinces participated, complemented by health innovation and procurement officials from the Department of Science, Technology & Innovation and the National Treasury.

Researchers included leading South African and international TB and vaccine research institutions such as the Aurum Institute, AHRI, SAMRC, NICD, SATVI, CAPRISA, Wits RHI, HE²RO, and VACFA. Participants ranged from CEOs and directors to TB modellers, programme managers, and clinical trial leads. International and Regional Organisations featured WHO at country, regional, and global levels, alongside the Clinton Health Access Initiative, and the London School of Hygiene & Tropical Medicine, providing global policy and technical perspectives.

Manufacturers and Industry partners included Biovac, Afrigen, and mining sector representatives, with senior leadership contributing to discussions on manufacturing capacity and early adoption.

Civil Society and Patient Advocacy voices were central, with representation from TB Proof, SANAC TB Technical Task Team, the Rural Health Advocacy Project, traditional leadership, and faith-based organisations, ensuring that community perspectives informed technical and policy debates.

Funders and Development Partners such as The Global Fund, the Gates Foundation, the Wellcome Trust, and Adduna Health Partners brought strategic investment perspectives, with senior programme officers and policy leads engaging in dialogue on financing and implementation pathways.

Developers including IAVI, BioNTech, and Gates MRI contributed product development insights, while Coordination and Rapporteurs from the Aurum Institute, Aquity Innovations, HSRC/UCT, and SAMRC ensured smooth facilitation and comprehensive documentation.

SOUTH AFRICA'S TB VACCINE READINESS WORKSHOP AGENDA

This comprehensive workshop brings together key stakeholders to address South Africa's urgent TB and HIV burden and develop a coordinated action plan for TB vaccine readiness.

OPENING SESSION

Objective: Set the tone for the workshop by framing South Africa's urgent TB and HIV burden, outlining the purpose of the meeting, and highlighting the need for coordinated action on TB vaccine readiness.

Themes:

- Welcome from the NDoH leadership and WHO South Africa to emphasise urgency, opportunity, and partnership.
- WHO update on alignment of South Africa's efforts with global initiatives and introduce the objective of the meeting.
- A lived experience perspective and community inclusion in vaccine planning.

Session I: National TB & Vaccination Strategies

Objective: Present and contextualise the TB burden, current TB prevention and care strategies, South Africa's immunisation infrastructure, and early policy considerations for vaccine introduction.

Themes:

- Epidemiological trends and programme progress in TB control were outlined, with a focus on the potential role of vaccination in reducing disease burden.
- National immunisation programme highlighted strengths and infrastructure gaps.
- Ongoing TB vaccine trials in South Africa: readiness for translation into policy.
- Insights into decision-making criteria for vaccine adoption by NAGI.

Session II: Evaluating the Impact and Evidence Base

Objective: Review the existing evidence and identify priority knowledge gaps to inform policy and investment decisions.

Themes:

- TB vaccine implementation research, progress and ongoing studies in SA.
- Consultation findings on projected demand: early market, procurement considerations.
- Global and national modelling studies: potential health impact and cost-effectiveness of vaccine introduction.
- Identified critical evidence gaps, including operational feasibility, long-term effectiveness, and economic modelling needs.

Session III: Prioritising Populations for Early Adoption

Objective: To examine equity, impact, and feasibility in early adoption, and collaboratively define priority groups and delivery approach.

Themes:

- Evidence-based frameworks for equitable and high-impact targeting were presented.
- Diverse stakeholder perspectives—from traditional leaders to clinical researchers—highlighted the balance between epidemiological targeting and community acceptance.
- Open discussion synthesised key considerations, identifying adolescents, high-transmission communities, and occupational risk groups as potential early targets.

Session IV: Policy & Introduction Pathways

Objective: To understand and align institutional, regulatory, and manufacturing considerations for TB vaccine introduction, and outline strategic factors for successful rollout.

Themes:

- Global and national manufacturing capacity, supply chain readiness, and procurement dynamics were discussed.
- Regulatory authorities shared approaches to expedite approval while ensuring safety and quality
- Financing strategies, equitable access frameworks, and the role of community engagement were emphasised as critical.

Session V: Enablers for TB Vaccine Introduction

Objective: To define priority actions across key domains through focused group work.

Breakaway Groups:

- Evidence for Policy and Investment: Cost-effectiveness data, budget impact analysis, and sustainability evidence.
- Strengthening Delivery Systems: Integration with TB-HIV programs, pharmacovigilance, private sector engagement.
- Manufacturing and Supply Readiness: Local production, regional procurement, and supply chain resilience.
- Regulatory Alignment and Policy Integration: Streamlined approval pathways and policy coherence.
- Financing and Access Strategies: Domestic and global funding mechanisms to ensure affordability and coverage.
- Driving Uptake and Trust: Community-led approaches to address hesitancy and build acceptance.

Session VI: Action Planning

Objective: To consolidate workshop input into a clear set of next steps for a TB vaccine readiness roadmap.

Themes:

- Synthesis Panel reflected on the strategic priorities emerging from all sessions.
- Facilitated discussion refined actionable recommendations, including timelines, responsibilities, and coordination mechanisms.
- Closing commitments from national and WHO leadership emphasised sustained multi-sectoral collaboration and integration with broader TB and immunisation strategies.

This workshop brings together expertise from public health, research, community advocacy, regulatory bodies, and international partners to develop a comprehensive TB vaccine readiness roadmap for South Africa.

KEY DISCUSSION AREAS, OUTCOMES, & EMERGING PRIORITIES

DAY 1: POLICY, FINANCING, AND IMPLEMENTATION

SESSION I: National TB & Vaccination Strategies
Summary of South Africa's TB epidemiology and where TB vaccine fits into national strategy

South Africa faces a significant tuberculosis (TB) burden, with an incidence rate of 427 cases per 100,000 population which far exceeds the global average of 134 (World Health Organization Global TB report for 2024). Professor Norbert Ndjeka, the Chief Director of the National TB program highlighted key challenges, including high HIV co-infection rates (230/100,000/year vs. the global average of 8.2) and drug-resistant TB (21/100 000/ year vs. the global average of 5). Although since 2015, the country has reduced TB incidence by 57%, mortality reduction remains low at 17%, and 56% of patients experience catastrophic costs due to TB treatment. Geographically, 10 districts account for 52% of TB cases, with five major metros contributing 35% of the national burden. The Eastern Cape has now surpassed KwaZulu-Natal as the highest-burden province.

South Africa's TB Recovery Plan, a plan to mitigate the impact of the COVID 19 pandemic and subsequent lock down, implemented three years ago, has improved treatment success rates to over 80% for drug-susceptible TB and 71% for drug-resistant TB. An effective TB vaccine that targets adults and adolescents could be transformative, potentially preventing 1.6 million persons from becoming ill from TB and 220,000 deaths between 2030 and 2050 (World Health Organisation: An Investment Case for New Tuberculosis Vaccines). However, multiple challenges must be overcome at a national level, alignment on the priority populations for vaccination and an optimal implementation strategy is needed to inform the supply needs, assess acceptability and proactively address health system gaps for efficient delivery. Assessment of cost-effectiveness and budget impact analyses in sub-national (provincial) settings will be needed to inform financing and introduction decisions. At a global level, efforts underway to ensure supply will meet global demand, through the WHO TB Vaccine Accelerator's Finance and Access committee, were highlighted: these aim to provide prompt policy recommendations and to identify novel financing solutions that could benefit all countries including those that are self-procuring.

Alignment with South Africa's Expanded Programme on Immunization (EPI)

Dr. Leslie Bamford, the Acting Director of Expanded Program on Immunizations (EPI) at NDoH, provided an overview of South Africa's EPI, which has historically focused on childhood vaccines but is expanding to include life course vaccinations. Currently, 80-85% of children are vaccinated, though zero-dose children are increasing. The program is fully integrated into public-sector primary healthcare, however there is limited private-sector involvement and poor inter-sectoral collaboration. A National Immunisation Strategy is currently under development.

Funding constraints pose a challenge, as vaccines are procured through national tenders using the equitable share budget. Severe staffing shortages also impact the program, with only six of the 12 national-level EPI staff positions filled while many provincial positions also remain open which further complicates program implementation and oversight. New vaccine introductions follow a structured process, including regulatory approval from SAHPRA, technical recommendations from the National Advisory Group on Immunisation (NAGI), securing financing and establishing procurement, and demand generation. Lessons from HPV vaccination (85-90% coverage via schools) and COVID-19 vaccination (50% adult coverage vs. a 70% target) highlight the critical role of demand generation and ensuring vaccine acceptability.

Ecosystem of TB and TB Vaccine Decision-Making Bodies

NAGI plays a central role in evaluating new vaccines. Dr. Waasila Jassat, Chair of the TB Vaccines Working Group at NAGI, explained that NAGI comprises 14 members and nine working groups, including a newly established TB vaccine working group. NAGI aligns with WHO's Preferred Product Characteristics (PPCs) for TB vaccines, which outline preferred attributes for vaccine efficacy, safety, schedule and regimen to guide vaccine developers. To date, only M72/AS01$_E$ has met attributes for vaccine efficacy in a phase 2b clinical trial. This candidate is currently in a phase 3 efficacy trial.

NAGI uses the PICO (Population Intervention Comparator Outcome) framework for evidence review and the GRADE framework (Grading of Recommendations, Assessment, Development and Evaluation) for transparent development of recommendations, considering public health priorities, equity, cost-effectiveness, and acceptability. Regulatory approval by the South African Health Products Regulatory Authority (SAHPRA) must precede NAGI deliberations. With regards to considerations for potential off-label use of TB vaccines (for IGRA negative, uncontrolled HIV, younger adolescents, lactating where there won't be sufficient data available), NAGI would need to balance public health value against regulatory status, using structured evidence assessments and clear risk-benefit analyses. Cost-effectiveness is a key criterion for vaccine adoption, requiring economic evaluations to inform decisions on procurement, affordability, and sustainable financing.

Other key stakeholders include the EPI and TB programmes and implementation research consortia; community advisory groups will also be required to ensure that vaccine introduction is evidence-based and community-informed.

TB Vaccine Candidates for Early Adoption
Professor Angelique Luabeya, from the South African TB Vaccine Initiative SATVI, presented the global TB vaccine pipeline, with 15 candidates under development, although only eight are actively recruiting in trials. Key candidates include:

- M72/AS01$_E$: Phase 3 trial in 15-44 years, with 60% of 20,000 participants recruited in South Africa, sponsored by the Gates Medical Research Institute. (At time of preparation of the report, fully recruited.)
- MTBVAC: Phase 2b in adolescents and adults and Phase 3 in infants, sponsored by IAVI.
- BNT164a1 and BNT164b1 (mRNA TB vaccines): Phase 2a trial, the first of a mRNA TB vaccine in Africa, sponsored by BioNTech.
- H107e/CAF10b: Phase 1 trial, sponsored by States Serum Institute.
- ID93/GLA-SE: Phase 2 trials, for both prevention and adjunct therapy.

SATVI scientists are also driving the development of an mRNA vaccine whose antigen selection is informed by correlates of risk of TB disease identified in large prospective clinical studies. Significant knowledge gaps include the absence of clinically validated correlates of protection, no data on efficacy in high-risk populations including those who have previously had TB disease, and the potential duration of vaccination-induced immunity. South Africa's clinical trials capacity in TB vaccine assessment is unique globally, and as such the country leads generation of TB vaccine trial data

Criteria for Vaccine Introduction in South Africa

Key considerations from NAGI perspective for TB vaccine adoption include:

- Efficacy: WHO PPCs propose at least 50% efficacy for adolescents/adults, though there may be specific settings in which a vaccine with lower efficacy may be cost effective.
- Safety & Regulatory Approval: SAHPRA and WHO prequalification, although the latter is not a pre-requisite for South Africa
- Cost-Effectiveness: Economic evaluations must justify procurement and sustainable financing.
- Health System Readiness: Integration with existing vaccination platforms (e.g., school health services for adolescents, primary healthcare for adults. EPI clinics for postpartum women).
- Demand Generation: Community engagement to address confidence/hesitancy and ensure uptake.
- Off-label use of TB vaccines (before full licensure for all target groups) may be considered if supported by strong evidence and risk-benefit analysis.
- Consider engaging early for regional country harmonisation for regulatory approval and with the established African Medicines Agency to leverage many of the African regulators into a collective alignment with TB Vaccine approach.

SESSION II: Evaluating The Impact and Evidence Base for TB Vaccine Introduction In South Africa

This session of the TB Vaccine Workshop examined critical aspects of TB vaccine implementation in South Africa, focusing on impact assessment, implementation research, priority populations, and evidence gaps. The discussions brought together modelling experts, implementation scientists, and public health stakeholders to develop critical insights and important considerations for successful TB vaccine introduction.

Potential Impact of TB Vaccine Introduction Implementation Science Research for Novel TB Vaccine Delivery in South Africa

Professor Limakatso Lebina from the African Health Research Institute (AHRI) presented on the critical role of implementation science in preparing for the introduction of novel TB vaccines, with a focus on bridging the gap between research evidence and real-world practice. The central objective outlined was to proactively use the lead time before a TB vaccine becomes available, projected within the next few years, to ensure a swift and effective rollout, thereby avoiding delays in determining the right messaging for target populations, delivery methods, and strategies to encourage uptake.

The presentation framed the challenge using a marketing model, suggesting that successful vaccine introduction requires careful consideration of the "4 Ps":

- **Product:** The attributes of the vaccine itself, such as safety profile and a preference for a one-dose regimen.
- **Place:** The locations and platforms for delivery, including clinics, pharmacies, or community settings, alongside the associated storage and logistics requirements.
- **Price:** The cost considerations, encompassing both health system costs and potential costs to vaccine recipients.
- **Promotion:** The strategies for vaccine acceptance, including community engagement and the role of local influencers.

The core of the presentation was dedicated to detailing a specific, ongoing implementation science research study led by AHRI in collaboration with The Aurum Institute and supported by a grant from the Gates Foundation. The study aims to co-develop an integrated delivery model and determine optimal strategies to enhance the uptake of a novel TB vaccine in South Africa. The multi-faceted research plan to achieve this includes several key components:

A systematic literature review is underway to synthesize existing evidence and identify persistent gaps. This will be followed by a comprehensive stakeholder mapping and influence analysis to categorize and develop tailored engagement strategies for all relevant parties. The research will also conduct participatory workshops with health system leadership, providers, policymakers, and researchers to collaboratively design potential delivery models for adolescent and adult vaccination, informed by the anticipated characteristics of leading candidates like M72/AS01$_E$ and MTBVAC.

To ground the work in community perspectives, the study will facilitate community dialogues across at least four provinces, utilizing trained Community Advisory Boards to gather local understandings of TB, perceptions of a new vaccine, and determinants of acceptance. The preferences identified through workshops and community input will then be quantitatively tested using discrete choice experiments with both community members and health providers to understand the trade-offs they are willing to make. Finally, the most promising integrated delivery model will be piloted within an existing vaccine program, such as those for HPV or in antenatal care settings, to assess its real-world feasibility.

The anticipated outputs of this research program include a recommended, co-developed integrated model for TB vaccine delivery that leverages existing health programs for cost-effectiveness, a detailed map of stakeholder influence and networks, and robust data on community perspectives to inform strategies for enhancing vaccine uptake. In summary, the presentation emphasized that a comprehensive body of implementation research is actively being planned and initiated to address the critical "Place" and "Promotion" aspects of vaccine introduction, with the goal of ensuring the health system and communities are fully prepared for a successful rollout.

Stakeholder Consultations on Vaccine Demand

Deanne Goldberg from Clinton Access initiative (CHAI) presented insights from a recent stakeholder consultation process undertaken to understand the potential demand and introduction scenarios for a novel TB vaccine in South Africa. The project, supported by the Wellcome Trust and the Gates Foundation and involving consultations with more than 120 stakeholders across nine high-TB burden countries.

South Africa's high TB burden and unique dynamics, including its significant population of people living with HIV (PLHIV) and the presence of other high-risk groups such as household contacts, healthcare workers, prisoners, and miners where detailed. South Africa benefits from strong political commitment to TB elimination and has experience as a clinical trial site for leading vaccine candidates. While the successful rollout of the HPV vaccine demonstrates capacity, the more complex challenge of achieving high coverage in adult populations, as seen with the COVID-19 vaccine, was also acknowledged.

Consultations revealed an extremely strong interest and political commitment for novel TB vaccine adoption, with stakeholders eager for its introduction as soon as possible. Key factors identified as critical for decision-making include clinical trial results, affordability, and robust cost-effectiveness analyses. The National Treasury expressed interest but emphasized the necessity of a strong health technology assessment to inform domestic resource mobilization. While a high vaccine efficacy of over 50% is preferred, stakeholders indicated they would consider a vaccine with lower efficacy if supported by a compelling cost-effectiveness argument and WHO recommendation. Preferred operational characteristics included a one-dose regimen, local manufacturing potential, manageable cold-chain requirements, and multi-dose vials.

Regarding implementation, a broad population approach targeting all eligible adolescents and adults was considered ideal. However, stakeholders recognized that a practical, risk-based approach may be necessary initially due to potential constraints in funding and supply. Priority populations identified include adolescents, PLHIV, healthcare workers, household contacts, miners, prisoners, and people living with diabetes. Collaboration between the TB programme, the Expanded Programme on Immunisation (EPI), school health services, and other primary healthcare platforms was highlighted as critical for efficient delivery. While starting in high-burden provinces and districts is a likely strategy, some stakeholders cautioned that a geographically targeted approach could raise concerns about stigma and require careful communication.

On timelines, there is a unanimous desire to introduce the vaccine immediately upon availability. However, delivery planning and procurement processes could potentially delay introduction by 12 to 24 months. The South African Health Products Regulatory Authority (SAHPRA) has indicated that TB vaccines will qualify for an expedited review, potentially halving the registration timeline. Regulatory approval will be for specific groups based on clinical trial data, with extra scrutiny for live attenuated vaccines in immunocompromised populations, though off-label use could be considered by the National Advisory Group on Immunisation (NAGI) following a risk-benefit assessment.

Based on these consultations, four potential demand scenarios were modelled, reflecting different levels of programmatic ambition and constraint:

- **Maximum Public Health Impact:** Aims to vaccinate all eligible adolescents and adults through a three-year nationwide catch-up campaign combined with routine adolescent immunization.
- **High Demand:** Focuses on accelerating impact by targeting adolescents and adults in high-burden provinces and high-risk groups with catch-up campaigns, plus routine immunization of adolescents.
- **Medium Demand:** Aims for long-term impact through routine immunization of adolescents and catch-up campaigns for high-risk groups only, excluding broader geographic targeting.
- **Low Demand:** The most constrained scenario, involving only the routine immunization of adolescents and catch-up for high-risk groups.

These scenarios project an increase in vaccine demand starting around 2030, with the scale and speed of rollout varying significantly based on the

Global Modelling Insights

Professor Richard White from the London School of Hygiene & Tropical Medicine provided a global perspective on the potential impact of novel TB vaccines, summarizing a decade of collaborative modelling work. The presentation aimed to translate complex modelling into accessible insights for planning and decision-making, framing models as tools to estimate future scenarios by testing different assumptions about vaccine characteristics and implementation strategies.

First established a framework for understanding vaccine types in models was established, distinguishing between:

- **Mechanism:** Prevention of Infection (POI) vaccines, which stop initial infection, and Prevention of Disease (POD) vaccines, which stop progression from infection to active disease.
- **Target Population Efficacy:** Pre-infection vaccines, which work only in uninfected individuals, and post-infection vaccines, which work only in those already infected.

Key uncertainties that models explore include a vaccine's efficacy level, its duration of protection, and the specific age groups or populations (such as people living with HIV) it is given to.

The presentation distilled findings from approximately 50 existing TB vaccine modelling publications into three key takeaways:

1. A Prevention of Disease (POD) vaccine would likely yield a faster and greater public health impact over the first 20 years compared to a Prevention of Infection (POI) vaccine, as it directly halts infectious cases. However, a POI vaccine would still be beneficial in high-transmission settings.
2. A vaccine that works in already infected (post-infection) individuals would have the fastest and greatest impact in settings like South Africa, China, and India due to the large number of people with existing TB infection. However, a vaccine effective in uninfected individuals would also be useful, particularly in high-transmission areas.
3. Vaccines with a relatively short duration of protection (e.g., five years) or modest efficacy (as low as 20%) could still be impactful and cost-effective in high-burden countries, offering hope even if candidates do not meet the highest efficacy targets.

Regarding targeting, the modelling literature consistently indicates that the greatest burden lies with adults and adolescents, making them the priority for vaccination. Protecting this group also indirectly protects children by reducing transmission sources. The critical need for a vaccine that is safe and effective for people living with HIV was also underscored.

The presentation then highlighted critical evidence gaps that will persist even after Phase III trial results are available. Specifically, the long-term duration of protection and the vaccine's efficacy in IGRA-negative individuals will not be known from the initial trial data. Modelling demonstrates that these two factors are crucial, as a vaccine with a longer duration or efficacy in IGRA-negative individuals would have a substantially greater population-level impact and cost-effectiveness. This underscores the urgent need for well-designed Phase IV studies to answer these questions post-licensure.

Finally, an overview of the recent WHO TB Vaccine Investment Case was provided. This analysis modelled a base-case scenario of a POD vaccine with 50% efficacy and 10-year duration, rolled out to adolescents and adults in 105 countries over a 20-year introduction period. The results projected that such a vaccine could, over 25 years, prevent 44 million TB cases, 25 million courses of drug treatment, and 5 million deaths globally. The analysis found that at a cost of five dollars per course, the vaccine would be cost-effective in most high-burden countries, including South Africa, and could even be cost-saving from a societal perspective when patient costs are included. It was also noted that with equitable targeting, the vaccine could significantly benefit the poorest populations and increase GDP across low- and middle-income countries.

For a high-burden country like South Africa, the key implications are that a POD vaccine effective in infected individuals is highly desirable. Even a vaccine with lower efficacy or shorter duration could be cost-effective and transformative. Success will depend on targeting adults and adolescents, potentially through campaigns to achieve rapid coverage, ensuring the vaccine is safe for people living with HIV, and prioritizing Phase IV studies to quickly generate evidence on duration of protection and efficacy in IGRA-negative populations

SA-Specific Modelling

Mmamapudi Kubjane from the University of the Witwatersrand presented on South African-specific modelling studies that assess the potential impact of novel TB vaccines. The presentation provided an overview of insights from existing literature, identified key evidence gaps in current models, and outlined a roadmap for future modelling work to be integrated into projects such as WellMod, the Thembisa TB model, and collaborations with The Vaccines for Africa Initiative (VACFA) at the University of Cape Town.

A review of existing mathematical modelling literature, which included both epidemiological and health economic analyses evaluated outcomes including TB incidence, mortality, and cost-effectiveness, and examined vaccines with varied characteristics. These characteristics encompassed the mechanism of action differentiating between prevention of disease and prevention of infection; the target population based on IGRA status, and variables such as coverage levels, duration of protection (ranging from 2 to 10 years), and vaccine efficacy (modelled from 20% to 100%).

Key insights from this body of modelling work indicated a prevention of disease vaccine was identified as the most impactful for reducing future morbidity, though a prevention of infection vaccine could also yield significant benefits in a high-transmission setting like South Africa. **The analyses indicated that even a vaccine with an efficacy as low as 20% could be cost-effective and potentially cost-saving.** In terms of implementation, routine vaccination strategies were found to be the most feasible and cost-effective but supplementing them with mass campaigns could substantially increase overall impact. Targeting adolescents and adults was projected to yield the greatest impact and be highly cost-effective, while targeting the general population would have a broader impact at a higher cost. Focusing specifically on people living with HIV was shown to be a cost-effective and efficient strategy; however, vaccinating irrespective of HIV status would lead to a greater population-level impact. The presentation then detailed critical gaps in the current modelling landscape that require further investigation. These gaps include understanding the long-term impact of a prevention of infection vaccine on future morbidity, the importance of an individual's latent TB status at vaccination, and the vaccine's efficacy, safety, and duration of protection in priority populations not included in current trials. Other gaps involve modelling the impact of targeting specific groups like healthcare workers and people with comorbidities, assessing the feasibility and resource needs of different delivery strategies, and evaluating vaccine acceptability and confidence. Further work is needed to determine how to efficiently integrate vaccination into existing programs and to conduct health economic analyses comparing vaccination to other TB interventions.

Planned future modelling work includes incorporating stakeholder-informed data on coverage, rollout timing, and priority populations into the WellMod project, alongside a study collecting data on latent TB prevalence and vaccine acceptability in key groups. The South African Tembisa TB model will be updated to include a vaccine component and integrated with local program costs to build a national investment case. This will help determine the optimal mix of interventions and how a TB vaccine compares to other measures. Additionally, through a collaboration with VACFA on the TB-TIMBER (Tuberculosis integrated model- based evidence and recommendations) project, efforts will be made to ensure that model-based evidence effectively informs the policy decisions of national immunization technical advisory group

Late-Stage TB Vaccine Pipeline: Assessing Risks and Critical Evidence Gaps

Prof. Willem Hanekom from AHRI focussed on two key areas: the gaps and risks associated with late-phase TB vaccines that may soon become available, and the gaps in data for specific target populations. On review of the pipeline of late-phase vaccine candidates, three were highlighted which are considered most advanced: M72/$AS01_E$, MTBVAC, and VPM1002.

Results from the phase 2b trial of the subunit vaccine M72/$AS01_E$, where a sensitivity analysis involving more rigorous endpoints showed higher efficacy, and where efficacy appeared to increase over time, suggest that the vaccine will show efficacy in its current phase 3 trial. However, a significant risk for implementation is that a manufacturing partner has not been identified/announced to date. Technology transfer to a newly identified partner will take time; therefore, there is a risk of suboptimal vaccine supply if an efficacy signal is shown in 2028.

Two concerns were raised surrounding the live attenuated whole mycobacterial vaccine MTBVAC. First, trials of the current live attenuated whole mycobacterial vaccine BCG showed an inverse association between efficacy and mycobacterial exposure, i.e., Mtb infection. Whether MTBVAC would therefore be effective in IGRA-positive individuals will have to be demonstrated; IGRA+ persons are targeted in the current phase 2b trial of the candidate. Second, a live attenuated whole mycobacterial vaccine may not be safe in people living with HIV (PLHIV), particularly in those whose HIV is not well-controlled or even undiagnosed - questioning how such a vaccine would be rolled out in a setting of high HIV prevalence. For the live attenuated whole mycobacterial vaccine VPM1002, a recombinant BCG, it was noted that two efficacy trials have been completed over two years ago without the results having been published.

Due to these gaps and risks with the leading candidates, a recommendation was made that a key outcome of the workshop should be a focus on accelerating discovery and development of novel candidates, to populate the clinical pipeline from the left.

Moving to target population gaps, a clarification was provided that the M72/AS01E and MTBVAC trials are designed to test efficacy in preventing symptomatic TB disease in HIV-uninfected IGRA+ adolescents and adults. Both studies will include a limited evaluation of the protective effect against asymptomatic TB. Safety and immunogenicity in well-controlled PLHIV and IGRA-negative individuals are also evaluated, but efficacy assessment in these populations will not be possible, for sample size reasons.

Specific populations for which critical data is lacking were then detailed:

- IGRA-negative individuals: Data was presented showing that 25-60% of different South African populations are IGRA-negative. Efficacy evaluation would have to be conducted post-licensure.
- People with well-controlled HIV: Efficacy evaluation post-licensure will be needed.
- People with uncontrolled HIV: It was highlighted that 2.3 million people in South Africa are living with HIV and are not virally suppressed. There will be no data on the safety, immunogenicity, or efficacy of any vaccine in this group.
- People who have had TB before: It was noted that 15-20% of people with TB in South Africa would have had TB before. A previous, small trial where M72/AS01E was administered to this population and to persons with TB disease toward the end of their course of antimicrobials, was terminated due to large skin reactions. This also requires post-licensure evaluation.
- There are several other groups for which safety, immunogenicity and efficacy data would ultimately be needed, including adolescents <15 years of age, children, the elderly, and people with silicosis. Pregnant and lactating persons are currently excluded from efficacy trials; regardless, it is likely that a subunit vaccine like M72/AS01$_E$ would be used “off-label,” whereas a whole bacterial vaccine like MTBVAC would likely require post-licensure evaluation.

SESSION III: Prioritising Populations for Early Adoption and Strategies to Deliver

This session shifted the focus from the strategic 'why' to the practical 'who' and 'how' of TB vaccine introduction. Building on the epidemiological and modelling evidence, participants worked to identify which populations should be prioritized for early vaccination to maximize impact and equity. The discussion also critically assessed the delivery strategies, integration points, and system-level requirement; from cold chain to healthcare workers; needed to turn vaccine policy into successful practice within the South African context.

Additional Populations for Consideration: Evidence Status and Data Gaps

The discussion identified several priority populations requiring special consideration regarding vaccine implementation. Healthcare workers emerged as a clear high-priority group, with data showing 8-10 times greater TB risk compared to the general population. Current clinical trials are generating efficacy data for this group and other adult populations (15–44-year-olds who are IGRA positive), which will be available at licensure.

However, significant evidence gaps remain for several key populations:

- Efficacy in IGRA negative adults (representing 25-60% of South Africans)
- Safety, immunogenicity and efficacy in people living with undiagnosed or uncontrolled HIV
- Safety, immunogenicity and efficacy in pregnant and lactating persons
- Safety, immunogenicity and efficacy in elderly populations (>45 years)

These groups will require targeted and prioritised Phase 4 post-marketing studies to evaluate vaccine safety and effectiveness. Particular attention must be paid to generating evidence for populations typically excluded from efficacy trials but representing significant portions of South Africa's TB burden.

Equity Considerations in Early Adoption and Geographic Stratification

The session emphasized that equitable distribution does not imply equal allocation, but rather strategic targeting of resources to areas and populations of greatest need. Key equity considerations include:

Geographic Prioritization:	Focus on five metropolitan areas accounting for 35% of national TB cases High-burden provinces Informal settlements with documented high transmission rates Mining communities, particularly gold mining areas with silica exposure risks
Demographic Equity:	Special strategies needed for adult men (35+ years) who face double the TB incidence of women but are less likely to access healthcare Migrant populations and mobile workers often missed by routine health programs People in informal employment without workplace health access
Implementation Approach:	Adopt lessons from HIV testing programs that successfully reached 15 million people annually Develop transparent communication frameworks to explain prioritization decisions Engage traditional leadership structures to reach underserved male populations

Integration with existing TB programs (e.g., screening, treatment)

The successful rollout of TB vaccination in South Africa will require strategic integration with existing TB prevention, screening, and treatment programs to maximize efficiency and impact and a focus on simple delivery approaches. Key integration opportunities include leveraging HIV clinics, where people living with HIV (PLHIV), a high-risk group for TB, already access regular care. By incorporating vaccination into ART visits, South Africa can efficiently reach this vulnerable population. Additionally, workplace health programs, particularly in high-risk sectors such as mining and healthcare, should be strengthened to include TB vaccination alongside occupational health screenings.

Household contact tracing presents another critical integration point. Offering vaccination to close contacts of TB patients could help prevent progression to TB disease while maintaining continuity with existing case-finding efforts. For broader population coverage, school-based vaccination programs modelled after successful HPV vaccine delivery could be adapted for adolescent TB vaccination campaigns.

To reduce stigma and improve uptake, lessons from HIV advocacy should be applied, including engagement with religious leaders, traditional healers, and community influencers. Messaging should create greater awareness about TB and normalize TB vaccination as a public health measure rather than targeting only high-risk individuals, avoiding potential stigmatization. Finally, future vaccine candidates with potential therapeutic benefits may eventually be integrated into TB treatment regimens, though this will depend on clinical trial outcomes.

Cold chain and healthcare workforce readiness.

South Africa's immunization program has experience managing cold chain requirements, but TB vaccine introduction will necessitate targeted assessments and potential upgrades. Most leading candidates, such as M72/AS01$_E$, require standard 2–8°C refrigeration, which aligns with existing EPI cold chain capacity. However, mRNA-based TB vaccines (e.g., BNT164) may require ultra-cold storage at select sites, necessitating localized infrastructure investments. Temperature monitoring systems must also be audited to ensure stability during transport and storage, particularly in rural and high-burden areas. The EPI program will require strengthening and support especially in terms of pharmacovigilance and health information management.

The healthcare workforce will play a pivotal role in vaccine delivery, yet staffing constraints remain a challenge. The national EPI program currently operates with limited staff and without implementing partner support, highlighting the need for expanded human resources ahead of a 2028/9 rollout. Additionally, healthcare workers themselves, who face an 8–10 times higher TB risk, must be prioritized both as recipients and advocates for vaccination.

Lessons from COVID-19 vaccine hesitancy among health workers underscore the need for targeted engagement to build confidence in TB vaccines. Strengthening occupational health programs will be critical not only for vaccinating healthcare workers but also for ensuring their safety as frontline providers. Private-sector collaboration, including pharmacies and corporate workplace clinics, could further extend reach. With four years remaining before anticipated vaccine availability, South Africa must address these logistical and workforce gaps to ensure a smooth and equitable rollout.

DAY 2: STAKEHOLDER ENGAGEMENT & ROADMAP

SESSION IV: Policy & Introduction Pathways

Manufacturing and Supply Considerations

Dr. Alexander Schmidt from Gates MRI emphasized the strength of the existing evidence base and clinical research capacity in South Africa, noting that the country hosts the best HIV and TB clinical researchers in the world and possesses the most comprehensive dataset for decision-making regarding the M72/AS01$_E$ vaccine candidate. The phase III trial enrolled 20,000 participants, with 13,000 in South Africa across 34 sites, participants are attending study visits through endpoint (110 incident confirmed TB disease episodes) and includes a significant biobank of samples from 10,000 participants at multiple time points, enabling detailed correlates of protection research. The discussion highlighted the intention to seek a permissive label indication for the prevention of TB in people 15 years of age and older, without restrictions based on IGRA or HIV status, pending discussions with the health authority.

Regarding manufacturing and supply, while specific negotiations with commercial manufacturers are confidential, the guiding principles focus on maximizing public health impact, availability, accessibility, and equity. The process involves scaling up manufacturing to commercial scale and seeking a manufacturer/s with technical capability, experience in supplying vaccines in low- and middle-income countries, and a presence in high-burden countries, aiming for an affordable and sustainable price based on volume. The presentation format for M72/AS01$_E$ will be a two-dose, two-vial presentation stored at 2-8°C with a vaccine vial monitor.

The CEOs of BIOVAC and AfriGen provided a joint overview of the South African and continental vaccine manufacturing landscape, emphasizing their complementary roles as local end-to-end manufacturers. They acknowledged the historical perception of South Africa's capability is focused on clinical research and fill-finish manufacturing for local supply. However, stressed that the country is actively working to plug gaps in the value chain and expand its capabilities.

A key point highlighted was the move beyond addressing only local needs to responding to global health demands, illustrated by BIOVAC's oral cholera vaccine project, which includes local drug substance manufacturing, a first for the country and aims for pre-qualification and export. South Africa is building end-to-end capability across multiple platforms and projects, such as PCV14 for GAVI, and is proficient not only in absorbing technology transfers but also in developing and exporting technology locally, as seen in the mRNA capability developed by AfriGen and transferred within the country.

The importance of operating within a broader continental ecosystem was emphasized, with reference to African Union and Africa CDC initiatives and a snapshot of African manufacturers expected to achieve pre-qualification by 2030, showing a significant number of South African entities aiming for end-to-end production. The discussion also stressed the critical need for demand forecast certainty to ensure financial sustainability, policy coherence across government departments to support local manufacturing, and the necessity of a robust pipeline of products to maintain viable operations.

The presentation highlighted the strength of the integrated ecosystem in South Africa, which includes end-to-end capacity from discovery and clinical trials to commercial manufacturing, facilitated by academic-private partnerships and early regulatory engagement. This ecosystem supports multi-product development, including two mRNA-based TB vaccines in development with local ownership and partnerships. The need for innovative funding mechanisms was emphasized to bridge the critical period between phase 3 trial completion and commercial manufacturing, ensuring that locally developed vaccines can reach the clinic. The overall message was that South Africa has built a foundation for sustainable vaccine manufacturing with continental relevance and is poised to expand its impact with the right support and coordination.

With coordinated action, the country could transition from reliance on imported vaccines to becoming a net exporter of TB vaccines by the end of the decade, provided financing and policy barriers are addressed. The establishment of a national vaccine manufacturing council to coordinate between industry, regulators, and health authorities was suggested as a priority next step.

SAHPRA Regulatory Pathways and Considerations for TB Vaccines

Dr. Boitumelo Semete-Makokotlela, CEO of the South African Health Products Regulatory Authority (SAHPRA), began by emphasizing the importance of early regulatory engagement in the TB vaccine development process to enable collaborative discussions on knowns and unknowns.

The presentation first outlined the standard regulatory process for vaccine approval in South Africa. A critical initial requirement is the identification of a local applicant to submit the dossier and manage post-registration activities, though the vaccine itself does not need to be manufactured locally. SAHPRA would require a Good Manufacturing Practice (GMP) inspection of the production facility. As a member of the Pharmaceutical Inspection Co-operation Scheme (PICS), SAHPRA can recognize GMP licenses from other member authorities, but may still conduct its own inspection if deemed necessary. The assessment itself involves a thorough review of the complete dossier, including Chemistry, Manufacturing, and Controls (CMC), pre-clinical data, and clinical trial information. While SAHPRA utilizes reliance pathways to recognize assessments from WHO-listed authorities or those with WHO prequalification, the anticipation for a novel TB vaccine is that SAHPRA may be among the first regulators to receive the dossier, potentially necessitating a full, independent assessment. Finally, like all vaccines in the country, any approved TB vaccine would be subject to mandatory lot release testing by SAHPRA's WHO-accredited laboratory to confirm the potency and quality of each batch.

Focusing on TB-specific considerations, the presentation noted that prevention of disease is the relevant efficacy endpoint for regulatory evaluation. While a validated correlate of protection is not an immediate prerequisite for licensure, immunogenicity data and a demonstrated clinical benefit are required. A plan for post-licensure studies to confirm the vaccine's effect in broader populations would also be a key part of the regulatory deliberation.

The presentation detailed several available regulatory pathways, all of which would be accelerated due to TB's designation as a priority disease:

- **Full Priority Review:** A comprehensive assessment of the entire dossier conducted on an accelerated timeline.
- **Reliance Pathways:** An abridged review based on the assessment and approval of a trusted regulator (a WHO-listed authority) or a WHO prequalification. The ability to use this pathway can be complicated if the manufacturing site for the South African application differs from the one approved by the reference regulator.
- **EU-Medicines for All (EU-M4All) Mechanism:** A collaborative procedure where the European Medicines Agency (EMA) assesses the dossier in partnership with a national regulator like SAHPRA and the WHO. A positive outcome through this mechanism could lead to SAHPRA registration within approximately 90 days.

The presentation also highlighted continental collaboration, noting that SAHPRA is a WHO Benchmarking Maturity Level 3 (ML3) authority for vaccines. A memorandum of understanding (MOU) among eight African ML3 regulators enables them to rely on each other's assessments. This means a SAHPRA approval could facilitate accelerated registration in other signatory countries, such as Nigeria and Ghana.

Finally, the critical post-approval responsibilities were underscored. This includes overseeing any post-registration studies stipulated in the risk management plan and robust pharmacovigilance to monitor Adverse Events Following Immunization (AEFIs) in collaboration with the scientific community. The presentation concluded by reaffirming SAHPRA's commitment to applying rigorous scientific processes while utilizing flexible and collaborative regulatory mechanisms to enable timely access to safe, quality, and efficacious TB vaccines.

The WHO TB Vaccine Accelerator Council's Finance and Access Working Group

Tara Prasad, representing the World Health Organization's Department of Immunization, Vaccines, and Biologics, presented on the work of the TB Vaccine Accelerator's Finance and Access Working Group. The group was established in February 2025 and is co-convened by WHO, the Government of South Africa, and Gavi, the Vaccine Alliance. Its formation was prompted by the advancement of late-stage TB vaccine candidates, with the goal of ensuring an equitable and impactful global rollout by proactively addressing financing and access challenges.

Unlike traditional vaccine markets that rely on high-income countries to drive initial commercial incentives, the goal for TB vaccines is to ensure high-burden countries receive access first, regardless of income level. This requires a different model that galvanizes the buying power of middle-income countries and coordinates equitable access across many affected nations. The "chicken and egg" dynamic of vaccine markets was highlighted: country demand, financing, and readiness influence manufacturer decisions on production scale and pricing, while supplier decisions on manufacturing and distribution influence countries' ability to procure and introduce the vaccine. The working group's objective is to break this cycle to prevent delays and access gaps.

The overall objective of the working group is to promote timely, equitable, and sustainably financed access to affordably priced new TB vaccines in all countries driven by public health need, while also fostering long-term, viable supply. This translates into several key goals: ensuring an adequate and rapid supply to meet global demand; fostering competition among multiple suppliers; converting public health need into realized country demand through sustainable financing (both domestic and external); and supporting regionally diversified manufacturing to ensure a resilient supply chain.

The working group's composition is designed to be practical and action-oriented, bringing together stakeholders with expertise in vaccine access and financing and those who have a key role to play in taking forward the recommendations and solutions. This includes global and regional procurement agencies, development banks, academia, civil society, financiers, regional partners, and high-burden countries. The group also consults with industry and product development partners.

The work plan for 2025 focuses on first understanding the status quo through a series of technical analyses, including:

- Mapping existing licensing agreements and access provisions for late-stage candidates to identify potential gaps.
- Analysing the access and financing plans of five high-burden countries to understand readiness and needs at the country level.
- Assessing the global financing landscape to estimate funding needs and identify gaps, given the current decline in official development assistance for health and national fiscal constraints.
- Developing a 10-year demand and supply projection to provide an understanding of the global market and comparison of supply and demand projections to identify any gaps.

Based on these analyses, the group will brainstorm potential solutions and present its findings in a report to be launched at the G20 ministerial meeting in November 2025 in South Africa. This report will outline what is needed and who needs to act to catalyse access. The subsequent years will focus on designing and implementing these solutions.

In the context of the workshop, the critical role of the South African government was emphasized. As a high-burden middle-income country and a co-convener of the working group, South Africa is positioned to leverage its buying power to influence the global market, create certainty for suppliers, and foster solidarity to ensure access for lower-income countries. The imperative of regional manufacturing on the African continent was also underscored as a key component of a sustainable solution







Building Community Trust as a Foundation for TB Vaccine Uptake

Russell Rensburg health advocate and director from the Rural Health Advocacy Project (RHAP) emphasized that the core of any successful vaccine introduction is trust. Trust was defined as the foundation of vaccine acceptance, encompassing confidence in the safety and efficacy of the vaccine itself, the health system that delivers it, and the healthcare workers who administer it.

While hesitancy existed prior to the pandemic, COVID-19 brought the issue to the forefront. Key findings from local studies on COVID-19 vaccination including one study in Mpumalanga found that barriers to vaccination included a lack of information on eligibility, not knowing where to get vaccinated, concerns about side effects, and inconvenient hours and locations for distribution. The study concluded that increasing rates would require addressing safety concerns, building confidence in efficacy, clarifying eligibility, and improving physical access for younger populations and men. Another study highlighted that vaccine acceptance was influenced by factors such as age, race, education, and geography, and argued that communication strategies must be part of broader trust-building measures focused on relationships, transparency, participation, and justice, including the use of peer-to-peer strategies and credible messengers.

These lessons when then connected to the context of tuberculosis. It was noted that TB is already a "low trust issue," evidenced by the tens of thousands of patients who are missed by the health system each year and the high number of deaths. The significant barrier of TB-related stigma was highlighted, with data from the Stigma Index indicating that a substantial proportion of people diagnosed with TB experience internalised stigma, and a study by TB Proof finding that 96% of people with TB experienced some form of anticipated or enacted stigma, which affects engagement across the entire care cascade. This existing environment of stigma and mistrust, combined with persistent health system challenges and the anticipated resurgence of misinformation, creates a complex backdrop for a future TB vaccine rollout.

A key opportunity for building trust and preparing for vaccination was identified in the recently launched National TB Campaign. This ambitious campaign, which aims to administer over five million tests, was presented as a critical platform. Its potential to find more patients and provide a deeper understanding of the TB epidemic was noted. The campaign's public-facing dashboard was singled out as a particularly valuable transparency mechanism, similar to what was used during COVID-19, which can provide real-time testing data and build public understanding and trust in the health system's efforts. The multi-sectoral nature of the campaign and the involvement of civil society were also highlighted as strengths that can strengthen community systems and lay the groundwork for vaccine delivery.

The presentation concluded by framing the next two to three years of the TB campaign as a crucial period for learning and preparation. The data gathered will provide insights into hard-to-reach populations, specifically men, who are a key target for both testing and future vaccination. By effectively using this information to improve engagement and service delivery, the health system can build the foundational trust necessary for the successful introduction of a TB vaccine. The takeaway stressed the importance of including more civil society voices in these discussions to help simplify and communicate messages effectively to the communities that need to be mobilized.

SESSION V: Enablers For TB Vaccine Introduction in South Africa

Feedback from the breakaway sessions

Group 1: Generating evidence for policy and investment

Presenters: Dr. Noriah Maraba, Prof Von Gottberg & Dr. Waasila Jassat

The group's deliberations made critical distinctions between the types of evidence required for regulatory approval versus public health policy decisions. While regulatory approval processes primarily assess safety, quality and efficacy through controlled clinical trials, policy recommendations demand additional evidence about real-world effectiveness, cost-effectiveness considering implementation feasibility, and population-level impact. This differentiation is particularly crucial for TB vaccines, where target populations may have limited representation in pre-licensure studies.

The group proposed a phased implementation strategy incorporating demonstration sites to generate essential effectiveness data for priority populations. This adaptive approach would initially focus on gathering real-world evidence for PLHIV, IGRA-negative persons, and those with a history of TB or other higher risks of TB disease progression. These demonstration sites would serve dual purposes: generating crucial effectiveness data including pharmacovigilance while simultaneously strengthening health systems for broader rollout.

Significant evidence gaps were identified for several vulnerable populations that are frequently excluded from clinical trials. These include pregnant women, older adults (beyond age 45), and individuals with comorbidities like diabetes, all of whom face elevated TB risks but lack specific safety and efficacy data. It was emphasized that these gaps should not preclude vaccine access but rather trigger the need, plans and budget for targeted post-marketing surveillance.

To address these limitations, it was strongly recommended to conduct comprehensive post-licensure studies to monitor real-world effectiveness and pharmacovigilance across diverse populations. These phase IV studies should be integrated with routine health information systems and include long-term follow-up to assess Adverse Event Following Immunisation (AEFIs) and duration of protection.

The importance of pairing implementation with robust pharmacovigilance systems capable of detecting rare adverse events and evaluating effectiveness in routine program conditions was also highlighted.

The proposed demonstration site and associated evidence generation framework balances the urgency of TB control with scientific rigor, advocating for progressive expansion of vaccination as data accumulates from learning sites and post-marketing surveillance. This approach aims to maximize public health impact while ensuring continuous monitoring of safety and effectiveness across all key populations.

Group 2: Strengthening delivery systems
Presenter: Dr. Lindiwe Mvusi

Group 2 emphasized leveraging South Africa's existing Expanded Programme on Immunization (EPI) as the foundational platform for TB vaccine delivery, aligning with its ongoing transition to a life-course vaccination approach. This integration aims to maximize efficiency, utilizing existing infrastructure, cold chain systems, and trained personnel while minimizing duplication of efforts.

A hybrid delivery model was proposed, combining facility-based services with targeted outreach initiatives, anchored by primary healthcare (PHC) as the operational command centre. This approach ensures accessibility for high-burden populations, including hard-to-reach groups (e.g., men), while maintaining strong linkages to routine health services. There is a need to gather evidence on patient preferences in terms of delivery approaches and proactively address vaccine hesitancy.

Critical system gaps were identified, requiring urgent attention:

1. Human resources: Additional staffing and training are needed to support rollout, particularly for outreach teams and EPI team.
2. Data systems: Strengthened digital health infrastructure is essential for real-time monitoring, coverage tracking, and adverse event reporting.
3. Cold chain capacity: Assessments must evaluate current EPI storage capabilities (vial size will be key), distribution and logistics capabilities, with upgrades planned for high-volume areas.

The group stressed learning from past vaccine rollouts, such as COVID-19 and HPV, to:

- Optimize demand generation (e.g., community engagement, stigma reduction).
- Refine logistics (e.g., last-mile delivery, multi-dose vial management).
- Address equity gaps in underserved regions.

Addressing these priorities can build a resilient, adaptable system capable of delivering TB vaccines effectively while strengthening overall immunization services within South Africa.

Group 3: Manufacturing and supply readiness Presenters: Dr. Morena Makhoana & Prof Mohlopheni Jackson Marakalala

South Africa possesses significant and immediate capability to produce TB vaccines across multiple technological platforms. Of the four key platforms discussed, mRNA, whole cell, subunit, and viral vector, the country currently has installed manufacturing capacity for three, with only the viral vector platform requiring activation. For the M72/AS01$_E$ candidate specifically, the group confirmed that domestic capabilities are already in place across the production chain: BioVac has capability for antigen production, AfriGen has capability for adjuvant manufacturing, and Aspen has capability for lyophilisation/ freeze-drying processes.

The group emphasized that South Africa has the potential to become a competitive manufacturer of TB vaccines but stressed that achieving this would require coordinated scale-up efforts supported by guaranteed demand. For this capability to be competitive and sustainable, however, it must be supported by scale that extends beyond the domestic market. While South Africa is a significant end-user due to its high disease burden, manufacturing must be coupled with regional and global procurement strategies, particularly within SADC and other low- and middle-income countries, to achieve viability.

The group strongly advocated for decisive leadership and coordinated government action to commit to local manufacturing, align various departments, and engage global partners. This is urgently needed to position South Africa not merely as a buyer, but as a strategic hub for supplying TB vaccines to the rest of the Global South, thereby capturing the full value chain for which the foundational clinical research is already occurring in the country. This would not only strengthen health security but also create a sustainable pathway for local vaccines.

Group 4: Regulatory alignment and policy integration Presenter: Prof Helen Rees

The group provided clarity on South Africa's vaccine governance framework, emphasizing the distinct but complementary roles of SAHPRA as the regulatory authority responsible for product approval and NAGI as the policy advisory body making vaccine recommendations.

The regulatory pathway discussion centred on the requirements for licensure and the formulation of a post-licensure risk management plan based on the existing data from clinical trials. This data (M72/AS01$_E$) includes studies involving approximately 18,000 IGRA positive individuals, 1,000 IGRA negative individuals, and 1,000 people living with HIV (both IGRA positive and IGRA negative). The current study population is limited to ages 15-45, with pregnant women formally excluded, though a small number of pregnancies within the trial is anticipated given the size of the study and will be documented. It is also anticipated that individuals with asymptomatic TB and diabetics are included.

It was recommended and agreed that a formal regulatory discussion must be initiated between the Gates MRI, as the potential applicant, and SAHPRA. The purpose of this meeting would be to review the existing data, assuming positive safety and efficacy signals, and to identify data gaps. In the event of a positive efficacy signal, a permissive licensure recommendation from SAHPRA is conceivable, potentially stating the vaccine can be used in "people at

risk of TB." This recommendation could specify the age group from the trial 15-45 or be broader,15 and older. The suggestion was to be silent on HIV status in the initial label, as safety and some immunogenicity data for people living with HIV will be available, though primarily from those who are well-controlled on antiretrovirals (ARVs).

Key data gaps and subsequent next steps for post-licensure studies were identified for several specific populations. For people living with HIV, particularly those who are uncontrolled or severely immunocompromised, efficacy data is lacking, and post-licensure immunogenicity studies were proposed, though their design was acknowledged as challenging. For pregnant women, it was strongly recommended that this be carefully studied post-licensure due to high adolescent pregnancy rates (adolescents and adults) in the target demographic. An immediate next step is to strengthen the pregnancy register (Ubomi Buhle Pregnancy Exposure Registry), assimilating baseline data on pregnancy, maternal and infant outcomes to provide context for future safety monitoring. A formal Phase IV study stratifying participants by trimester was proposed. For older populations (up to age 45), diabetics, individuals with asymptomatic TB, and those with a history of TB, post-licensure immunogenicity and safety studies were recommended.

A critical conclusion was that funding will be required for these post-licensure studies. It was recognized that while current funders may be hesitant to commit ahead of efficacy results, a strong, pre-negotiated plan with the regulator would make securing funding more likely once positive results are confirmed. The need to proactively identify funding sources was emphasized, including a specific discussion on whether the Department of Health should fund initiatives like the pregnancy register or if third-party funding should be sought. The overall next step is to develop a robust and timely plan for these studies in alignment with SAHPRA to avoid delays post-licensure.

Group 5: Financing and access strategies
Presenter: Tara Prasad

The group flagged the critical importance of initiating early preparatory work for TB vaccine financing, despite the product still being in development. They highlighted three priority areas requiring immediate attention to ensure successful implementation.

First, they emphasized the urgent need for South Africa-specific cost-effectiveness analyses that compare TB vaccination against other TB interventions, evaluate resource allocation trade-offs, and calculate the absolute costs of a national vaccination program. These economic evaluations will be essential for securing government and donor funding commitments.

Regarding financing mechanisms, the group proposed several innovative approaches. They recommended exploring public-private partnerships, particularly with the mining sector which bears a disproportionate TB burden, as well as establishing multi-country volume guarantees among high-burden nations to achieve economies of scale. The COVID-19 pandemic response offers valuable lessons in rapid procurement and delivery that should inform TB vaccine planning, including leveraging existing platforms like the NDoH central procurement system. To coordinate these complex financing preparations, they advocated for establishing a local multi-sectoral task force on financing. This body would bring together representatives from government, private sector, development partners, and civil society to develop comprehensive financing strategies, negotiate pricing agreements, and align stakeholders around a shared implementation roadmap.

Group 6: Driving vaccine uptake and community trust
Presenter: Russell Rensburg

Group 6's findings revealed that low public awareness and knowledge gaps about TB pose a major obstacle to vaccine acceptance. To address this, they recommended expanding and reinforcing the National End TB Campaign to ensure accurate, accessible information reaches communities.

Several key barriers to vaccine uptake were identified:

1. Testing requirements: The need for IGRA (Interferon-Gamma Release Assay) testing before vaccination could deter participation due to limited access or perceived complexity.
2. Logistical challenges: A multi-dose vaccine regimen, combined with sputum testing requirements, may reduce compliance, particularly in hard-to-reach populations.
3. Uncertainty for high-risk groups: The lack of clear efficacy data for PLHIV raises concerns about vaccine effectiveness in this vulnerable group, potentially lowering uptake.

To overcome these challenges, the group proposed targeted community engagement strategies, including:

- Collaborating with trusted leaders: Engaging traditional chiefs, religious figures, and local influencers to build trust and disseminate information.
- Leveraging existing platforms: Utilizing school health programs and sports clubs to reach younger populations and broader audiences.
- Empowering TB champions: Training and mobilizing local advocates (e.g., survivors or healthcare workers) to share personal experiences and encourage vaccination.

By integrating these approaches, vaccination efforts can be more inclusive, accessible, and community-driven, ultimately improving TB prevention and control.

SESSION VI: Action Planning, Reflections and Next Steps

The reflections during the final workshop session highlighted a strong collective commitment to advancing TB vaccine readiness and identified several critical areas for immediate focus. Key among the discussion points was the recognition that even a vaccine with 20% efficacy would have a significant impact, underscoring the urgency of the work ahead. Critical cross-cutting enablers for success were consistently emphasized, including unwavering political commitment, a steadfast focus on equity in access, and the foundational need to build and maintain community trust.

A clear pathway for decision-making was outlined, noting that the National Department of Health will require a formal recommendation from the National Advisory Group on Immunisation (NAGI) for ministerial approval. The regulatory pathway, as presented by SAHPRA, may involve a permissive recommendation and collaboration with other African agencies, with immediate actions possible to strengthen national pharmacovigilance systems and pregnancy registers. On financing, the urgent need for South Africa-specific cost-effectiveness data was stressed to inform budget allocation, alongside the proposed creation of a multi-sectoral task team and a dedicated fund for TB vaccines.

Several actionable **next steps** were outlined, which have been grouped into the following priority areas for immediate attention:

- **Evidence Generation for Decision-Making:** This includes finalizing a framework for post-licensure studies, commissioning South African cost-effectiveness analyses, and initiating plans for demonstration project sites to gather critical implementation and safety data upon rollout.
- **Strengthening Systems for Delivery:** Key actions include optimizing pharmacovigilance and pregnancy registers, conducting a thorough assessment of provincial readiness, and undertaking targeted health system strengthening, with a specific focus on addressing the capacity constraints within the Expanded Programme on Immunisation (EPI) identified for leading the rollout.
- **Community Engagement and Communication:** A major priority is to devise a comprehensive community engagement and co-creation strategy. This involves launching research to understand and address TB-specific vaccine confidence and hesitancy, developing simple and effective messaging, particularly around the concept of lower efficacy, and leveraging existing structures like the NTB campaign, religious leaders, and schools to ensure access to hard-to-reach populations like men.
- **Coordination and Financing:** Establishing a dedicated financing working group is essential to conceptualize a sustainable funding model, which may include a specific TB vaccine fund and exploring domestic and innovative financing mechanisms. Furthermore, there is a need to clearly conceptualize what a regional Southern African approach entails to guide future collaboration

CONCLUSION

The South Africa TB Vaccine Workshop marked a critical first step in the country's concerted effort to prepare for the introduction of new TB vaccines for adults and adolescents. By bringing together key stakeholders, this engagement has set the foundation for alignment on priorities and a collaborative, multi-sectoral approach to vaccine readiness. The discussions were rich with insights, generating innovative ideas while also highlighting the many unanswered questions that still need answers. The lead time before these vaccines become available (projected for 2028–2029) provides a crucial window to address these gaps, refine strategies, and ensure South Africa is fully prepared for a successful rollout.

The roadmap developed as a result of these engagements will serve as a guiding framework, further aligning stakeholders around clear priorities, from health system strengthening and community engagement to regulatory preparedness and sustainable financing. This is only the beginning; many more multistakeholder dialogues will follow and co-ordination will be key as we work toward our shared goal of ending TB in our lifetime.

It was an incredibly humbling experience to witness the depth of expertise and commitment. We extend our deepest gratitude to all participants for their invaluable contributions, which have set this vital initiative in motion. Together, we are laying the groundwork for a future where TB vaccines become a transformative tool in South Africa's fight against this epidemic.



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World Health Organization
South Africa

APPENDICES

Appendix 1: Full attendee list

Specific Organisations/Institutions	Names	Role
NDOH TB Cluster	Prof Norbert Ndjeka	NDoH Chief Director, TB Cluster
NITAG	Dr Waasila Jassat	NITAG TB working group chair
Africa Health Research Institute	Prof Willem Hanekom	Executive Director
World Health Organization – South Africa Office	Dr Nkateko Mkhondo	Technical Officer for TB
South African TB Vaccine Initiative, University of Cape Town	Prof Angelique Luabeya Kany Kany	Chief Research Officer / TB Prevention Task Team Chair
TB Proof	Ms Phumeza Tisile	Patient advocate
WHO African Regional Office	Dr Lynda REY	WHO African Regional Routine Immunization Officer
National Department of Health	Hon Dr Aaron Motsoaledi	Minister of Health
National Department of Health	Mr Ramphelane Morewane	Acting Deputy Director General
National Department of Health	Dr Sandile Buthelezi	NDOH Director General
NDOH Expanded Programme on Immunization	Dr Lesley Bamford	Market Access Director
NDOH Expanded Programme on Immunization	Ms Elizabeth Maseti	Deputy Director: Expanded Program On Immunisation
National Department of Health	Ms Marione Schonfeldt	Senior Pharmaceutical Policy Specialist, Health Products Procurement
NDOH TB Cluster	Dr Lindiwe Mvusi	Director, Drug-susceptible TB, TB Cluster, NDOH
Witwatersrand Reproductive Health & HIV Initiative	Prof Helen Rees	SAHPRA Board Chair Executive Director Wits RHI
South African Health Products Regulatory Authority	Dr Boitumelo Semete-Makokotlela	SAHPRA CEO
Department of Health	Feni Moditswana MOTSHWANE	Integrated School Health Programme (ISHP) manager
Department of Science, Technology, & Innovation	Ms Glaudina Loots	Director, Health Innovation
National Treasury of South Africa	Jonathan Daven	TBC
Department of Health	Ms Hushendree Naicker	NAGI Secretariat
KwaZulu-Natal Provincial TB Programme	Ms Jacqueline Ngozo	TB Director
Northern Cape Provincial TB Programme	Ms Sheila Katz	TB Director
Free State Provincial Department of Health	Ms Chaciwe Maggy Majenge	EPI Manager
KwaZulu-Natal Provincial Department of Health	Ms Nomakhwezi Baloyi	EPI Manager
North West Provincial Department of Health	Ms Kelebogile Keothaile	EPI Manager

Specific Organisations/Institutions	Names	Role
Northern Cape - West End Hospital, Kimberley	Dr Clementina Duran Palma	TB Vaccine Site
Affordable Medicines Directorate	Ms Khadija Jamaloodien	Chief Director, Health Products Procurement
Affordable Medicines Directorate	Ruth Lancaster	Pharmaceutical Policy Specialist
The Aurum Institute	Prof Gavin Churchyard	Chair of the NIH/DAIDS Cross-Network TB vaccine Working Group
African Health Research Institute	Prof Limakatso Lebina	Director for Clinical Trials
South African Medical Research Council	Prof Fareed Abdullah	Director, Office of AIDS and TB Research
South African Medical Research Council	Ms Fatima Abrahams	Senior Programme Manager
National Institute for Communicable Diseases	Dr Shaheed Vally Omar	Centre Head of Tuberculosis, National Health Laboratory Service
National Institute for Communicable Diseases	Prof Anne von Gottberg	Chair, NAGI
South African TB Vaccine Initiative, University of Cape Town	Prof Mark Hatherill	Director of SATVI
Witwatersrand Reproductive Health & HIV Initiative	Prof Lee Fairlie	Director of Maternal and Child Health
CAPRISA	Prof Kogie Naidoo	Deputy Director and Head of Treatment Research Programme
Health Economics and Epidemiology Research Office	Dr Mmamapudi Kubjane	Researcher & TB modeller
World Health Organization – South Africa Office	Ms Shenaaz El-Halabi	WHO Representative for South Africa
WHO African Regional Office	Dr Jean Louis ABENA	WHO African Regional Advisor, TB
WHO IVB	Dr Birgitte Giersing	Team Lead, Vaccine Prioritization & Platforms, WHO IVB
WHO IVB	Ms Tara Prasad	Team Lead Vaccine Access
WHO Global TB Programme TB PCI	Dr Dennis Falzon	Team Lead, TB Prevention, Research, and Innovations
Clinton Health Access Initiative	Verena Damovsky	working on the global demand forecast
Clinton Health Access Initiative	Ms Deanne Goldberg	TB Access Programme Manager
Clinton Health Access Initiative	Omphile Ramokhoase	TB Access Programme Officer
LSHTM	Prof Richard White	Leading country consultations for WT
Biovac	Dr Morena Makhoana	CEO, Biovac
Afrigen	Prof Petro Terblanche	CEO
Mining sector	Dr Thuthula Balfour	Head of Health and Safety Minerals Council of South Africa
TB Proof	Ms Ingrid Schoeman	Director of Advocacy and Strategy
Rural Health Advocacy Project	Mr Russell Rensburg	Director
Traditional leadership representative	Prince Nhlanganiso Zulu	Zulu Royal Family
Interfaith representative	Rev Nicolas Bhengu	Reverend at Edendale Uniting Presbyterian Church
The Global Fund	Ms Yolisa Tsibolane	Director, Global Fund Programmes

Specific Organisations/Institutions	Names	Role
Gates Foundation	Prof Yogan Pillay	Director, HIV & TB Delivery
Gates Foundation	Mr Gaurang Tanna	Senior Programme Officer for TB
Gates Foundation	Dr Pren Naidoo	Public Health Management Consultant
Gates Foundation	Ms Ashling Mulvaney	Senior Programme Officer
Adduna Health Partners	Ms Sarah Ewart	Founder, Adduna Health
Wellcome Trust	Mr Jeremy Knox	Head of Policy
Wellcome Trust	Ms Rachel Hore	Global Policy and Advocacy Officer
IAVI	Ansuya Naidoo	IAVI
BioNTech	David Schellenberg	BioNTech
Gates MRI	Dr Alexander Schmidt	Gates MRI
Aurum Institute	Dr Priashni Subrayen	Technical TB Director
Aurum Institute	Mr Thobani Ntshiqa	Senior Research Manager
WHO country office	Mr Andani Makahane	Programme Assistant
Rapporteur 1 (Aquity)	Dr Refiloe Matji	CEO, AQUITY Innovations
Rapporteur 2 (Aurum)	Dr Noriah Maraba	Scientist
Rapporteur 3 (Aurum)	Dr Matsie Mphahlele	Technical Director
Rapporteur 4 (HSRC/UCT)	Prof Sizulu Moyo	Senior Research Director
Rapporteur 5 (MRC)	Prof Mohlopheni Jackson Marakalala	TB Research Centre director
Aurum Institute	Mikateko Tserema	Journalist
Aurum Institute	Salome Charalambous	Group Chief Health Officer
Aurum Institute	Mthokozisi Dube	Programme Manager TB Think Tank
Department of Science, Technology and Innovation	Modiegi Selematsela	Deputy Director
Aurum Institute	Kanya Ndaki	Communications Director
NDOH - Communications	Foster Mohale	NDoH Spokesperson
National Department of Health	Howad Kgogi	
National Department of Health	Sello Lenokane	
National Department of Health	Charity Bhengu	Journalism and Communications Specialist
National Department of Health	Sipho Senabe	Chief Director
South African Medical Research Council	Chake Niyonge	
South African National AIDS Council	James Kekana	Social Worker
XINHUA	Ephraim Mashishi	Photography Director
South African Broadcasting Corporation	Venesa Khwinana	Journalist
South African Broadcasting Corporation	Puseletso Mokoena	Journalist
South African Broadcasting Corporation	Zandile Myeza	Journalist
	Onkgopotse Koloti	

Appendix 2: Workshop Agenda
Advancing Policy and Decision-Making for TB Vaccine Introduction in South Africa: A Preparedness Workshop

Time	Topic	Speaker(s)
DAY 1		
08:15-08:45	Registration & Coffee	
OPENING SESSION		
Session Chairs: Mr Ramphelane Morewane & Prof Fareed Abdullah		
08:45-08:55	Welcome remarks	Dr Sandile Buthelezi
08:55-09:05	Remarks from WHO South Africa office	Ms Shenaaz El-Halabi
09:05-09:20	Perspectives from the Gates Foundation (meeting sponsor)	Prof Yogan Pillay
09:20-09:30	Efforts under the WHO TB Vaccine Accelerator	Dr Birgitte Giersing
09:30-09:40	Lived experience and the imperative of equitable access	Ms Phumeza Tisile
09:40-10:15	Photo Session	
SESSION I: NATIONAL TB & VACCINATION STRATEGIES		
To present and contextualise South Africa's TB burden, TB prevention and care, immunisation infrastructure, and early vaccine policy considerations to identify opportunities and challenges for introducing a new TB vaccine.		
Session Chair: Dr Nkateko Mkhondo		
10:15-10:35	TB in South Africa: Epidemiology, programme progress & vaccine potential	Prof Norbert Ndjeka
10:35-10:55	South Africa's Immunization Programme	Dr Lesley Bamford
10:55-11:15	TB Vaccine Trials in South Africa	Prof Angelique Luabeya
11:15-11:30	Key criteria for TB vaccine introduction: Insights from the National Advisory Group on Immunisations (NAGI)	Dr Waasila Jassat
11:30-12:00	Q&A with speakers on a panel	Facilitator: Dr Nkateko Mkhondo
12:00-13:00	Lunch	
SESSION II: EVALUATING THE IMPACT AND EVIDENCE BASE FOR TB VACCINE INTRODUCTION IN SOUTH AFRICA		
To review current evidence and identify priority knowledge gaps to support TB vaccine introduction decision-making in South Africa.		
Session Chair: Prof Anne Von Gottberg		
13:00-13:20	Overview of TB vaccine implementation research in South Africa	Prof Limakatso Lebina
13:20-13:40	Insights from consultations on future demand for TB vaccines in South Africa	Ms Deanne Goldberg
13:40-14:00	Global modelling insights on the impact of TB vaccination	Prof Richard White
14:00-14:20	Modelling vaccine introduction scenarios in South Africa	Dr Mmamapudi Kubjane
14:20-14:35	Gaps in the TB vaccine evidence base: From science to implementation	Prof Willem Hanekom
14:35-15:00	Open discussion: What evidence do we still need?	Facilitator: Prof Van Gottberg
15:00-15:30	Tea Break	
SESSION III: Prioritising populations for early adoption and strategies to deliver		
To examine equity, impact, and feasibility considerations for early TB vaccine adoption; and collaboratively identify priority populations and delivery strategies suited to South Africa.		
Session Chair: Dr Lindiwe Mvusi		
15:30-15:50	Setting the scene: Equity, impact, and feasibility in early vaccine adoption	Prof Mark Hatherill
15:50-16:10	Panel discussion: Perspectives on who should be prioritised and how	Prince Nhlanganiso Zulu, Prof Kogie Naidoo, Ms Jacqueline Ngozo, Dr Pren Naidoo, Dr Thuthula Balfour
16:10-17:00	Open discussion: Synthesis of key considerations, priority groups and practical strategies	Facilitator: Dr Lindiwe Mvusi
17:00-17:15	Day 1 Wrap-Up: Key takeaways	Mr Ramphelane Morewane
17:15-19:00	Networking reception	

DAY 2		
08:00-08:25	Coffee & Day 1 Recap	Prof Fareed Abdullah
SESSION IV: POLICY & INTRODUCTION PATHWAYS		
To clarify decision-making and regulatory processes for TB vaccine introduction, and identify enabling factors, financing mechanisms, and implementation strategies within national structures.		
Session Chair: Prof Norbert Ndjeka		
08:25-08:35	Global Manufacturing and Supply Considerations	Dr Alexander Schmidt
08:35-08:45	National Manufacturing and Supply Considerations	Dr Morena Makhoana, Prof Petro Terblanche
08:45-08:55	Regulatory preparedness	Dr Semete-Makokotlela
08:55-09:05	Overview of global strategies for equitable access and financing of TB vaccines	Ms Tara Prasad
09:05-09:15	Community engagement and vaccine acceptance	Mr Russell Rensburg
09:15-09:30	Q&A	Facilitator: Prof Ndjeka
SESSION V: Enablers for TB Vaccine Introduction in South Africa		
Breakout sessions to explore and define priority actions across key domains essential for successful TB vaccine introduction and uptake. Participants will join pre-assigned breakaway groups (see registration pack).		
Session Chair: Prof Fareed Abdullah		
09:30-09:40	Introduction to breakaways	Prof Fareed Abdullah
09:40-10:45	Breakaway Group 1: Generating Evidence for Policy and Investment This session will explore priority evidence needs to inform policy decisions, including cost-effectiveness analyses, budget impact assessments, and the data required to support vaccine adoption and sustainability within health systems.	Moderators: Prof Gottberg, Dr Waasila Jassat Rapporteur: Dr Noriah Maraba
09:40-10:45	Breakaway Group 2: Strengthening Delivery Systems for TB Vaccines Focusing on system readiness, this session will address delivery platforms, integration with TB-HIV and immunisation programmes, laboratory and pharma-covigilance capacity, and the role of private sector and surveillance systems in reaching target pops	Moderators: Dr Lindiwe Mvusi, Prof Limakatso Lebina Rapporteur: Dr Priashni Subrayen
09:40-10:45	Breakaway Group 3: Manufacturing and Supply Readiness This session will cover TB vaccine production and supply chain considerations, including global and regional manufacturing capacity, procurement planning, and ensuring timely and equitable availability of vaccines.	Moderators: Ms Khadija Jamaloodien, Dr Morena Makhoana Rapporteur: Prof Marakalala
09:40-10:45	Breakaway Group 4: Regulatory Alignment and Policy Integration Participants will discuss strategies for regulatory preparedness, including pathways for vaccine approval, coordination with national regulatory authorities, and the integration of TB vaccines into broader policy and guideline frameworks.	Moderator: Prof Helen Rees Rapporteur: Dr Matsie Mphahlele
09:40-10:45	Breakaway Group 5: Financing and Access Strategies This session will focus on domestic and international financing mechanisms, procurement strategies, and pathways to ensure equitable access to TB vaccines, especially in high-burden, low-resource settings.	Moderators: Prof Norbert Ndjeka, Ms Deanne Goldberg Rapporteur: Dr Refiloe Matji
09:40-10:45	Breakaway Group 6: Driving Vaccine Uptake and Community Trust Addressing the social dimensions of TB vaccine introduction, this session will highlight research and advocacy approaches to strengthen community engagement, build vaccine confidence, and overcome hesitancy.	Moderator: Mr Russell Rensburg Rapporteur: Prof Sizulu Moyo
10:45-11:00	Tea Break	
11:00-11:50	Breakaway feedback	Session Moderators
11:50-12:00	Remarks from the Minister of Health	Hon Dr Aaron Motsoaledi
12:15-13:15	Lunch	
SESSION VI: ACTION PLANNING		
To consolidate inputs into actionable recommendations, aligning policy, research, and stakeholder coordination to develop a draft roadmap for TB vaccine adoption.		
Session Chair: Dr Dennis Falzon		
13:15-13:30	Synthesis Panel: Reflections on workshop discussions	Dr Brigitte Giersing Prof Willem Hanekom
13:30-14:45	Facilitated Discussion: Suggestions for concrete next steps	Facilitator: Dr Dennis Falzon
14:45-15:00	Closing Session: Commitments & next steps	Prof Norbert Ndjeka, Ms Shenaaz El-Halabi

Appendix 3: List of Break- Aways, Moderators and Rapporteurs

Breakaway Session	Moderators	Rapporteurs	Recommended Participants
1. Generating Evidence for Policy and Investment	Dr Waasila Jassat & Anne von Gottberg	Dr Noriah Maraba	Prof Anne von Gottberg, Dr Waasila Jassat, Prof Willem Hanekom, Prof Angelique Luabeya, Prof Mark Hatherill, Dr Mmamapudi Kubjane, Prof Richard White, Dr Shaheed Vally Omar, Prof Fareed Abdullah, Dr Anthony Hawkridge, Dr Simangele Mthethwa, Dr Jean Louis ABENA; Prof Gavin Churchyard, Dr Dennis Falzon, Ms Glaudina Loots, Dr Pedro Alonso, Prof Lee Fairlie
2. Strengthening Delivery Systems for TB Vaccines	Prof Limakatso Lebina & Dr Lindiwe Mvusi	Dr Pria Subrayen	Dr Lindiwe Mvusi, Prof Limakatso Lebina, Dr Lesley Bamford, Ms Elisabeth Maseti, Ms Jacqueline Ngozo, Dr Sheila Katz, Ms Nomakhwezi Baloyi, Ms Maggie Majenge, Ms Refilwe Motsamai, Dr Clementina Duran, Dr Aaron Motsoaledi, Mr Xolela Somahela; Ms Mpho Keothaile, Dr Pren Naidoo
3. Manufacturing and Supply Readiness	Ms Marione Schonfeldt & Dr Morena Makhoana	Prof Mohlopeni Marakalala	Ms Marione Schonfeldt, Dr Morena Makhoana, Prof Petro Terblanche, Dr Stavros Nicolaou, Dr Alexander Schmidt, Ms Tammy Gopal, Ms Marione Schonfeldt, Dr Marta Tufet Bayona, Dr Suvanand Sahu, Mr Gaurang Tanna, Dr Charlie Weller
4. Regulatory Alignment and Policy Integration	Prof Helen Rees & Dr Boitumelo Semete-Makokotlela	Dr Matsie Mphahlele	Prof Helen Rees, Dr Boitumelo Semete-Makokotlela, Ms Tammy Gopal, Dr Mark Blecher, Ms Hushendree Naicker, Dr Nkateko Mkhondo, Dr Birgitte Giersing, Prof Yogan Pillay, Ms Fatima Abrahams
5. Financing and Access Strategies	Ms Deanne Goldberg &Prof Norbert Ndjeka	Dr Refiloe Matji	Prof Norbert Ndjeka, Ms Deanne Goldberg, Ms Ashling Mulvaney, Ms Tara Prasad, Ms Verena Damovsky, Mr Jeremy Knox, Dr Rupali Limaye, Ms Sarah Ewart, Mr Ramphelane Morewane, Ms Makaita Gombe, Ms Shenaaz El-Halabi, Dr Ansuya Naidoo, Ms Yolisa Tsibolane
6. Driving Vaccine Uptake and Community Trust	Mr Russell Rensburg	Prof Sizulu Moyo	Mr Russell Rensburg, Ms Phumeza Tisile, Ms Ingrid Schoeman, Prince Nhlanganiso Zulu, Rev Nicolas Bhengu, Ms Phumeza Tisile, Prof Kogie Naidoo, Mr Thobani Ntshiqa, Ms Feni Moditswana Motshwane, Dr Thuthula Balfour, Prof Charles Wiysonge

APPENDIX 4: TB Vaccine Workshop Steering Committee Members

Name	Organisation / Affiliation
Dr. Angelique Kanykany	University of Cape Town (UCT)
Dr. Birgitte Giersing	World Health Organization (WHO)
Dr. Charles Wiysonge	World Health Organization (WHO)
Dr. Jody Boffa	TB Think Tank
Dr. Nkateko Mkhondo	World Health Organization (WHO)
Prof. Norbert Ndjeka	National Department of Health, South Africa
Dr. Priashni Subrayen	Aurum Institute
Mr. Thobani Ntshiqa	Aurum Institute
Ms. Phumeza Tisile	Community Advocate (TB Survivor)
Prof. Rudzani Muloiwa	University of Cape Town (UCT)
Dr. Saskia den Boon	World Health Organization (WHO)
Dr. Waasila Jassat	Technical Support Unit (TSU)
Prof. Willem Hanekom	Africa Health Research Institute (Ahri)

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