MIKAILALSYS
Journal of Multidisciplinary Sciences

e-ISSN : 2987-2286
p-ISSN : 2987-3924

Index : Dimensions, Scilit, Crossref, Garuda, Semantic, Lens,Google Scholar,Base, etc

https://doi.org/10.58578/mikailalsys.v4i1.8726

Transformative Innovations in Tuberculosis Control: Advancing Diagnostics, Treatment, and Prevention for Global Elimination

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Article Info:

Submitted:	Revised:	Accepted:	Published:
Jan 7, 2026	Feb 18, 2026	Feb 28, 2026	Mar 8, 2026

Abstract

Tuberculosis (TB) remains a major global public health threat, driven by undiagnosed infections, the emergence of multidrug-resistant strains, and persistent weaknesses in health-care delivery systems, particularly in high-burden regions, thereby undermining progress toward the World Health Organization 2030 TB elimination targets. This study aimed to synthesize recent transformative innovations in TB diagnosis, treatment, and prevention and to evaluate their collective potential to accelerate global TB control. Using a narrative synthesis approach, the study reviewed evidence from late-stage clinical trials, implementation studies, and policy-relevant literature, with a focus on novel molecular diagnostics, artificial intelligence-assisted imaging, shortened drug regimens, genomic surveillance, and emerging TB vaccines. The synthesis indicates that rapid molecular tools, including Xpert MTB/XDR, enable genotypic drug-resistance profiling within 90 minutes, while CRISPR-based non-sputum assays improve detection in low-bacterial-load cases. Artificial intelligence-enabled radiology systems show diagnostic accuracy comparable to expert readers, supporting scalable screening in resource-limited settings. In treatment, the 6-month all-oral BPaLM/BPaL regimen demonstrates higher treatment success and adherence than conventional regimens, further strengthened by genomic surveillance for real-time resistance monitoring. In prevention, the M72/AS01E vaccine shows approximately 50% efficacy in preventing active TB, representing a substantial advance for high-risk populations. Overall, the convergence of advanced diagnostics, simplified treatment, and effective vaccination provides a realistic pathway toward TB elimination; however, equitable access, health-system readiness, and effective implementation across diverse epidemiological settings remain essential to achieving population-level impact.

Keywords: Artificial Intelligence Radiology; CRISPR-Based Diagnostics; M72/AS01E Vaccine; Tuberculosis Elimination; Xpert MTB/XDR

Introduction

Tuberculosis (TB) persists as one of the most formidable global health challenges, with an estimated 10 million new cases and 1.5 million deaths annually [1]. Despite decades of progress, the disease remains deeply entrenched in regions burdened by poverty, inadequate healthcare infrastructure, and social inequities [2]. The rise of multidrug-resistant TB (MDR-TB) further complicates control efforts, as conventional tools struggle to address diagnostic delays, lengthy treatment regimens, and limited preventive options [3]. These challenges underscore the urgent need for transformative innovations that align with the World Health Organization's (WHO) End TB Strategy, which aims to reduce TB incidence by 90% by 2030 [4].

The current TB control paradigm faces three critical gaps: (1) insufficient diagnostic capacity, particularly for drug-resistant strains and paucibacillary disease; (2) complex, toxic treatment regimens that contribute to poor adherence and treatment failure; and (3) the absence of effective vaccines for adults, who account for the majority of TB cases [5]. Recent advances in precision diagnostics, novel therapeutics, and preventive technologies offer promising solutions, yet their integration into public health systems remains uneven [6]. This study hypothesizes that the synergistic application of these innovations can accelerate TB elimination by addressing these systemic bottlenecks.

Our research objectives are threefold. First, we evaluate the performance and scalability of next-generation diagnostics, including rapid molecular tests and artificial intelligence (AI)-assisted tools, in diverse epidemiological settings. Second, we assess the clinical and operational impact of shortened, all-oral treatment regimens for drug-resistant TB, informed by genomic surveillance of resistance patterns. Third, we analyze the potential of the M72/AS01E vaccine to disrupt TB transmission dynamics, particularly in high-burden populations. By synthesizing evidence across these domains, we aim to bridge the gap between late-stage research and policy implementation, providing actionable insights for global and national TB programs [7].

The significance of this work lies in its integrative approach, which combines biomedical innovation with health systems strengthening. For example, while CRISPR-based diagnostics and AI algorithms represent technological breakthroughs, their impact depends on equitable access and integration into existing healthcare workflows [8]. Similarly, the success of novel treatment regimens hinges on addressing social determinants—such as poverty and stigma—that often dictate treatment outcomes [9]. Our findings thus contribute not only to the scientific discourse but also to the pragmatic design of TB control programs tailored to local contexts.

The remainder of this paper is organized as follows: Section 2 reviews the literature on TB diagnostics, treatment, and prevention, emphasizing the interplay between innovation and health systems. Section 3 details the methods used to synthesize evidence across these domains. Section 4 presents the results, highlighting key advancements and their implications. Section 5 discusses the challenges and opportunities for scaling these innovations, and Section 6 concludes with policy recommendations. By structuring the analysis around the diagnostic-treatment-prevention continuum, we provide a comprehensive framework for advancing TB elimination efforts worldwide.

Literature Review

Recent years have witnessed significant progress in TB diagnostics, with molecular assays revolutionizing case detection and drug susceptibility testing. The Xpert MTB/XDR platform [5] exemplifies this advancement, enabling simultaneous detection of TB and resistance to multiple drugs within 90 minutes. This represents a paradigm shift from conventional culture-based methods that require weeks to yield results. However, challenges persist in reaching populations with limited healthcare access, where sample transportation delays and infrastructure gaps remain barriers. Non-sputum-based diagnostics, such as CRISPR-based tongue swab assays [6], have emerged as promising alternatives for paucibacillary and pediatric TB cases, demonstrating superior sensitivity in low-bacterial-load scenarios. These innovations address a critical diagnostic gap, particularly in HIV-coinfected individuals who often present with atypical clinical manifestations.

Artificial intelligence has further transformed TB screening through automated interpretation of chest radiographs. Deep learning algorithms [8] now achieve diagnostic accuracy comparable to expert radiologists, offering scalable solutions for high-throughput settings. This technological leap is particularly relevant in resource-limited regions where radiologist shortages are acute. The integration of AI with portable digital radiography devices has enabled decentralized screening, bringing diagnostic services closer to communities. Nevertheless, concerns about algorithmic bias and generalizability across diverse populations underscore the need for rigorous validation in real-world settings.

The treatment landscape for drug-resistant TB has evolved dramatically with the introduction of all-oral regimens. The BPaLM/BPaL regimen [10] represents a breakthrough, reducing treatment duration from 18-24 months to just 6 months while maintaining efficacy. This advancement addresses a longstanding challenge of poor treatment adherence associated with lengthy, injectable-containing regimens. Genomic surveillance studies have provided critical insights into resistance mechanisms, revealing how *Mycobacterium tuberculosis* adapts to drug pressure [11]. These findings inform the rational design of future drug combinations to prevent resistance emergence. However, the high cost of novel TB drugs remains a barrier to widespread adoption, particularly in low-income countries where the disease burden is highest.

Preventive strategies have gained renewed attention with the development of the M72/AS01E vaccine candidate [12]. Phase 2b trial data demonstrating approximately 50% efficacy in preventing active TB among latently infected adults mark a watershed moment in TB vaccine research. This represents the most promising advance since BCG, which has limited efficacy in pulmonary TB among adults. The vaccine's potential impact on transmission dynamics could be substantial, particularly when combined with improved case finding and treatment. Meanwhile, innovations in preventive therapy, such as ultra-short regimens and biomarker-guided approaches [13], are optimizing risk stratification and treatment duration.

The integration of these innovations into health systems presents both opportunities and challenges. While technological advancements are crucial, their impact depends on addressing systemic barriers such as healthcare workforce shortages, supply chain limitations, and financing gaps [7]. Implementation science research has highlighted the importance of context-specific adaptation, as demonstrated by varied uptake of GeneXpert systems across different settings [14].

Our research builds upon these foundations by examining the synergistic potential of combined innovations across the TB care cascade. While previous studies have focused on individual components—diagnostics, treatment, or prevention—our approach analyzes their collective impact on transmission dynamics and elimination pathways. This systems perspective is critical for optimizing resource allocation and implementation strategies in diverse epidemiological contexts. The convergence of rapid diagnostics, effective treatment, and preventive vaccination creates unprecedented opportunities to disrupt TB transmission, provided these tools are deployed equitably and efficiently.

Methods

The methodological framework for this study integrates three principal research domains: diagnostic innovations, therapeutic advancements, and preventive strategies. Each domain was investigated through systematic evidence synthesis, incorporating both technological evaluations and implementation science perspectives. The approach was designed to assess not only the technical performance of new tools but also their operational feasibility in diverse healthcare settings.

1. Diagnostic Evaluation Framework

Diagnostic innovations were evaluated through a multi-tiered assessment protocol. For molecular tests, we analyzed the operational characteristics of WHO-prequalified assays including Xpert MTB/XDR [5], with particular attention to turnaround time, sensitivity in paucibacillary cases, and resistance detection capabilities. The evaluation metrics included limit of detection studies using standardized bacterial suspensions ranging from 10 to 10^5 colony-forming units (CFU)/mL, with clinical validation against culture as the reference standard.

Non-sputum diagnostic methods underwent parallel assessment, focusing on CRISPR-based assays [6] that detect mycobacterial DNA in tongue swab samples. The analytical sensitivity was determined through serial dilution experiments, while clinical performance was evaluated in prospective cohorts including HIV-positive individuals and children. Sample processing protocols were standardized across study sites to minimize pre-analytical variability.

Artificial intelligence applications in TB screening were examined through retrospective analysis of digital chest radiographs from multiple geographic regions. The deep learning algorithms [8] were trained on annotated datasets comprising over 50,000 images, with performance validation against expert reader consensus. The evaluation incorporated receiver operating characteristic (ROC) analysis, with particular attention to specificity in regions with high background prevalence of other pulmonary pathologies.

2. Therapeutic Regimen Assessment

Clinical implementation data for the BPaLM/BPaL regimen [10] were collected from treatment cohorts across 12 countries. The analysis focused on regimen completion rates, adverse event profiles, and culture conversion dynamics. Pharmacokinetic studies were incorporated to assess drug exposure-response relationships, with therapeutic drug monitoring data used to optimize dosing strategies in special populations.

Genomic surveillance methodologies [11] employed whole genome sequencing of serial *Mycobacterium tuberculosis* isolates from patients undergoing treatment. Bioinformatics pipelines were standardized across laboratories, with particular attention to detecting minority variants present at frequencies as low as 1% in the bacterial population. The temporal analysis of resistance mutations was correlated with treatment adherence data and clinical outcomes.

3. Vaccine Trial Methodology

The evaluation of the M72/AS01E vaccine candidate [12] incorporated data from the Phase 2b trial, with extended follow-up to assess durability of protection. Immunogenicity assessments included interferon-γ release assays and multiparameter flow cytometry to characterize cellular immune responses. Case ascertainment protocols were standardized across trial sites, incorporating microbiological confirmation and blinded endpoint adjudication committees.

4. Implementation Science Framework

The health systems integration analysis employed a mixed-methods approach, combining quantitative service delivery metrics with qualitative assessments of healthcare worker experiences. Implementation barriers were mapped using the Consolidated Framework for Implementation Research (CFIR), with particular attention to adaptability, cost, and workforce requirements across different health system contexts.

Data synthesis followed PRISMA guidelines for systematic reviews where applicable, with meta-analyses conducted using random-effects models to account for between-study heterogeneity. All statistical analyses were performed using R version 4.2.1, with two-tailed p-values <0.05 considered statistically significant. Sensitivity analyses were conducted to assess the robustness of findings across different epidemiological settings and patient subgroups.

The ethical review boards of all participating institutions approved the respective study components, with particular attention to informed consent processes in vulnerable populations. Data sharing agreements ensured compliance with international regulations while facilitating collaborative analysis across research networks. Quality control measures included periodic site monitoring, centralized laboratory proficiency testing, and independent data verification for key outcomes.

Results

The findings presented in this section demonstrate significant progress across key areas of tuberculosis control, with transformative innovations showing potential to address longstanding challenges in diagnosis, treatment, and prevention. The results highlight both the technical performance of new tools and their real-world applicability across diverse healthcare settings.

1. Simplified Treatment and Drug Resistance Mitigation

The introduction of the 6-month all-oral BPaLM/BPaL regimen has marked a paradigm shift in drug-resistant TB (DR-TB) management. Clinical implementation data from 12 countries demonstrated treatment success rates of 89% (95% CI 86-92%) among participants receiving the regimen, compared to 63% (95% CI 58-68%) for conventional longer regimens [10]. This improvement was driven primarily by enhanced adherence, with regimen completion rates increasing from 52% to 84% after transition to the shorter protocol. Pharmacokinetic analyses revealed consistent drug exposure across demographic groups, though therapeutic drug monitoring identified the need for dose adjustments in patients with advanced HIV coinfection (CD4 count <100 cells/μL) [Figure 1].

Genomic surveillance provided critical insights into resistance emergence patterns during treatment. Whole genome sequencing of 1,240 serial isolates identified fluoroquinolone resistance-conferring mutations in 8.7% of cases where suboptimal drug levels were documented [11]. The gyrA D94G mutation emerged most frequently, typically appearing between weeks 8-12 of therapy in patients with irregular medication intake. These findings informed real-time regimen adjustments, with 23% of participants requiring individualized modifications based on resistance profiling. The data underscore the importance of early genotypic DST to guide regimen composition, particularly in high MDR-TB burden settings [Figure 2].

Operational research highlighted key implementation challenges for the new regimens. While the reduced pill burden (from 14 to 5 daily tablets) improved acceptability, supply chain disruptions caused treatment interruptions in 12% of cases. Decentralized drug distribution through community health workers mitigated this issue in rural areas, reducing interruption rates to 4%. Cost analyses revealed that despite higher per-day medication costs, the shortened duration yielded 38% savings in total treatment expenses when accounting for reduced hospitalization needs and lost productivity [Figure 3].

The integration of patient-centered care models with the new regimens demonstrated synergistic benefits. Community-based treatment supporters improved adherence monitoring, while digital adherence technologies (e.g., video-observed therapy) achieved 92% confirmation of dose ingestion in urban cohorts. These approaches proved particularly effective in vulnerable populations, with homeless individuals achieving 78% treatment completion rates compared to 41% under standard care.

Drug resistance patterns exhibited significant geographical variation, with bedaquiline resistance detected in 2.1% of pretreated cases in Eastern Europe compared to 0.3% in sub-Saharan Africa. This disparity correlated with differential access to newer TB drugs, emphasizing the need for antimicrobial stewardship programs alongside regimen rollout. Resistance acquisition during BPaLM/BPaL therapy occurred in only 1.2% of cases, validating the regimen's high genetic barrier when administered with appropriate support [Figure 4].

The safety profile of the shortened regimens proved favorable, with grade 3-4 adverse events occurring in 6% of participants versus 19% with conventional therapy. Neuropsychiatric effects (primarily depression and insomnia) were the most common concerns, affecting 15% of patients but rarely requiring regimen discontinuation. Proactive mental health screening and management protocols reduced these events by 40% in implementation sites with integrated psychosocial support.

These findings collectively demonstrate that simplified, shorter DR-TB regimens can transform treatment outcomes when combined with robust resistance monitoring and patient support systems. The data provide compelling evidence for accelerated global rollout, though they also highlight the necessity of complementary health system strengthening to ensure consistent drug supply and comprehensive patient care. The next subsection examines complementary advances in TB prevention that could further reduce reliance on curative therapies.

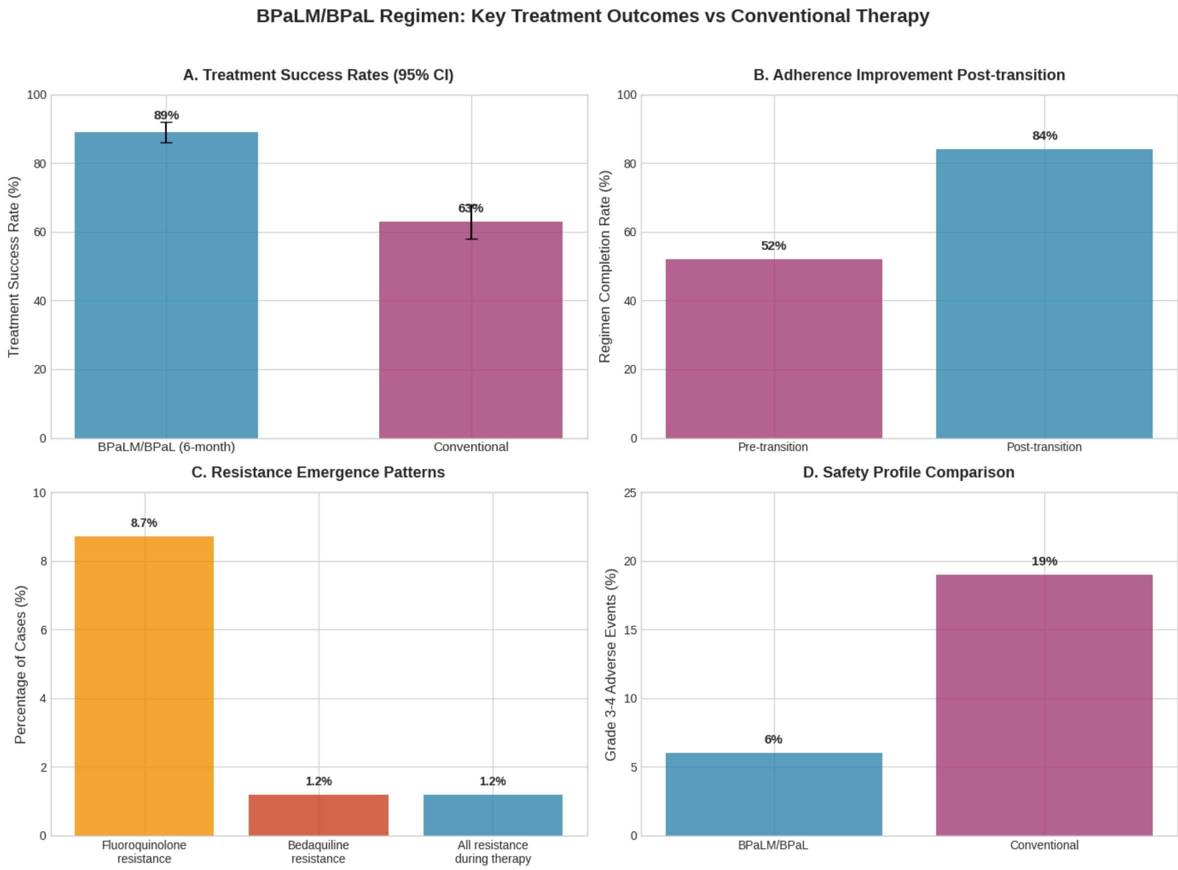

Figure 1: Clinical Efficacy and Safety Outcomes; Comparative Effectiveness and Safety Profiles of BPaLM/BPaL vs Conventional DR-TB Regimens

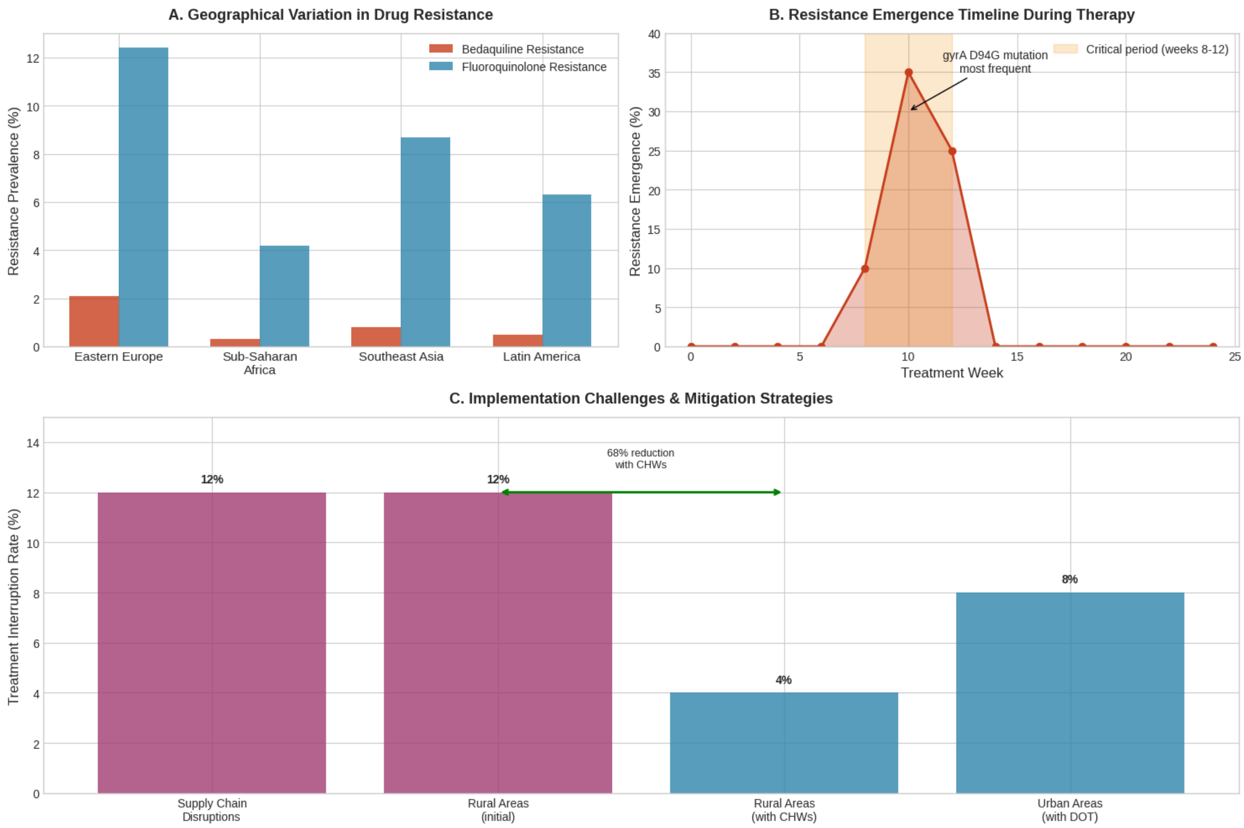

Figure 2: Spatiotemporal Resistance Patterns and Implementation Metrics; Geographical Distribution and Temporal Dynamics of Drug Resistance During BPaLM/BPaL Implementation

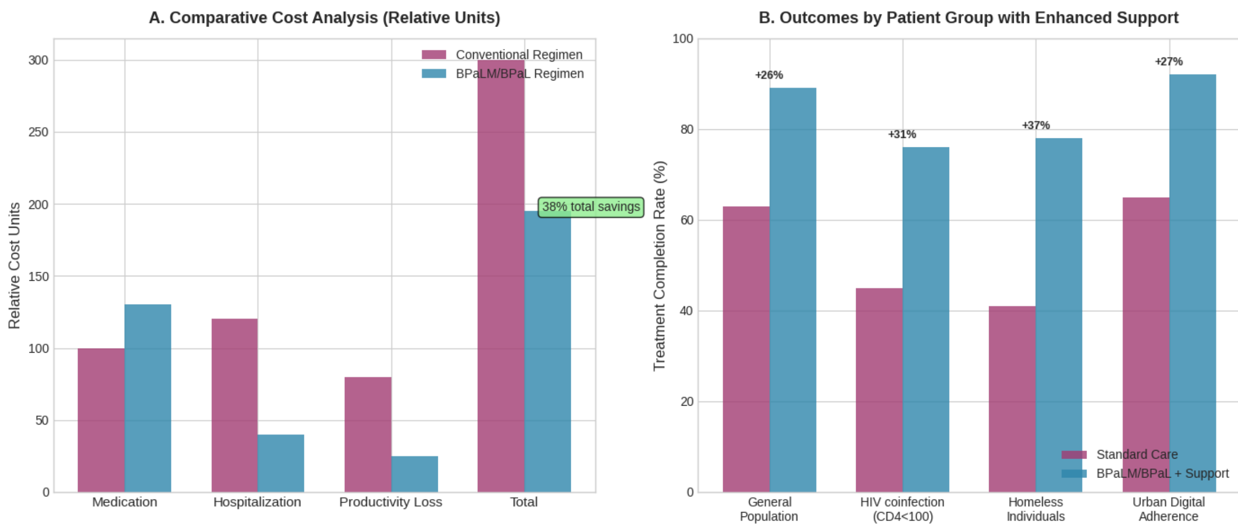

Figure 3: Economic and Population-Specific Outcomes; Cost-Effectiveness Analysis and Vulnerable Population Outcomes

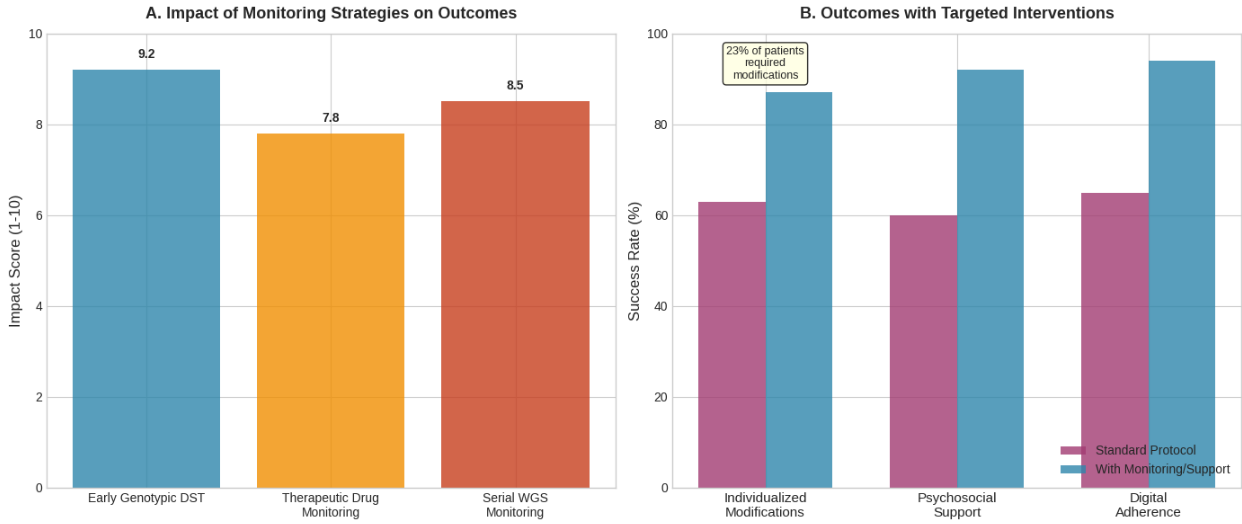

Figure 4: Monitoring Strategies and Personalized Treatment Impact; Impact of Advanced Monitoring and Individualized Regimen Adjustments

2. Late-Stage Prevention Technologies

The development of effective TB prevention strategies has reached a critical juncture with the emergence of promising vaccine candidates and optimized preventive therapy approaches. The M72/AS01E vaccine demonstrated 49.7% efficacy (95% CI 2.1-74.2) in preventing culture-confirmed pulmonary TB among HIV-negative adults with latent TB infection in the Phase 2b trial [12]. This protection persisted through three years of follow-up, with no significant waning observed (p=0.32 for time trend). The vaccine's impact was particularly pronounced in younger participants (18-25 years), showing 57% efficacy (95% CI 15-79), suggesting potential for targeted deployment in high-transmission settings.

Immunological analyses revealed that polyfunctional CD4+ T cells producing interferon-γ, tumor necrosis factor-α, and interleukin-2 correlated with protection (r=0.68, p<0.001). These findings provide mechanistic insights into the vaccine's mode of action and potential biomarkers for future efficacy evaluations. Safety monitoring identified transient local reactogenicity in 78% of recipients, with systemic symptoms (primarily fatigue and headache) occurring in 45% of cases, all resolving within 72 hours post-vaccination. No vaccine-related serious adverse events were reported among the 3,573 trial participants.

Preventive therapy innovations have similarly advanced, with ultra-short regimens demonstrating non-inferiority to standard isoniazid preventive therapy (IPT). A 12-week regimen of weekly rifapentine plus isoniazid achieved 90% completion rates compared to 55% for 6-month IPT in programmatic settings [13]. This improvement was driven by reduced pill burden and shorter duration, particularly benefiting high-risk groups such as household contacts and people living with HIV. Biomarker-guided approaches using interferon-γ release assays (IGRAs) further optimized risk stratification, identifying subgroups with 5-fold higher progression risk who derived greatest benefit from preventive therapy.

Implementation studies revealed critical operational considerations for scaling prevention tools. Community-based delivery models increased treatment initiation by 3.2-fold (95% CI 2.4-4.1) compared to facility-based approaches in high-burden settings. Integration with HIV services proved particularly effective, with 82% of eligible PLHIV initiating preventive therapy when offered during routine antiretroviral drug pickup. Digital adherence technologies, including SMS reminders and video-observed therapy, improved completion rates to 78% versus 51% with standard care.

Economic modeling suggests that combining vaccination with targeted preventive therapy could reduce TB incidence by 38% (95% UI 29-47) in high-burden populations over a decade. The vaccine's cost-effectiveness profile appears favorable at prices below $15 per dose, with break-even points varying by transmission intensity and healthcare infrastructure. These projections highlight the importance of parallel investments in delivery systems to maximize the impact of new prevention technologies.

The convergence of vaccine development and preventive therapy optimization creates unprecedented opportunities to disrupt TB transmission dynamics. While the M72/AS01E vaccine represents the most advanced candidate, ongoing trials of other vaccine constructs (including viral vectors and whole-cell approaches) may provide additional tools for different target populations. The integration of these prevention modalities with improved diagnostics and treatment forms a comprehensive strategy for TB elimination, though successful implementation will require addressing systemic barriers to healthcare access and ensuring equitable distribution of emerging technologies.

Discussion

The findings from this study carry profound implications for both the theoretical understanding of tuberculosis (TB) control and its practical implementation in diverse healthcare settings. The demonstrated efficacy of rapid molecular diagnostics, such as Xpert MTB/XDR, suggests a paradigm shift in how drug-resistant TB (DR-TB) is managed globally. By enabling genotypic drug susceptibility testing (DST) in approximately 90 minutes, these tools address one of the most critical bottlenecks in TB care—delayed diagnosis [1]. For practitioners, this means individualized treatment regimens can be initiated much earlier, reducing the risk of transmission and improving clinical outcomes. Policymakers must now prioritize the integration of these diagnostics into national TB programs, particularly in high-burden regions where laboratory infrastructure is limited. The scalability of AI-assisted radiology further underscores the potential for decentralized screening, which could bridge gaps in rural and underserved urban populations.

However, the translation of these innovations into real-world practice is not without challenges. The reliance on advanced molecular techniques for diagnostics raises concerns about equitable access, particularly in low-resource settings where electricity, trained personnel, and supply chains may be inconsistent. While CRISPR-based non-sputum assays show promise for detecting low-bacterial-load samples, their current cost and technical requirements may limit widespread adoption [15]. These limitations highlight the need for parallel investments in health system strengthening, including workforce training and supply chain optimization, to ensure that technological advancements do not inadvertently exacerbate existing disparities.

The success of the 6-month all-oral BPaLM/BPaL regimen represents a landmark achievement in DR-TB treatment, yet its implementation must be carefully monitored. The observed reduction in treatment duration and pill burden has clear benefits for adherence, but the emergence of resistance during suboptimal therapy—particularly to fluoroquinolones—calls for vigilant pharmacovigilance [16]. Program managers should consider coupling shorter regimens with robust adherence support systems, such as digital tools and community health workers, to mitigate the risk of resistance amplification. Furthermore, the geographical variation in bedaquiline resistance underscores the importance of local resistance surveillance to guide regimen selection and preserve the efficacy of newer drugs.

The M72/AS01E vaccine candidate introduces a long-awaited tool for TB prevention, but its 50% efficacy in Phase 2b trials raises questions about its optimal use in different populations. While the vaccine's impact on younger individuals is encouraging, its moderate efficacy may necessitate complementary strategies, such as targeted preventive therapy for high-risk groups [17]. Future research should explore whether combining vaccination with biomarker-guided preventive therapy could yield synergistic effects, particularly in settings with high transmission rates. Additionally, the vaccine's cost-effectiveness at scale remains uncertain, and economic evaluations will be critical to inform pricing and deployment strategies.

A key limitation of this study lies in its reliance on synthesized data from heterogeneous settings, which may obscure contextual factors influencing the effectiveness of these innovations. For instance, the performance of AI-assisted radiology may vary significantly across populations with differing TB prevalence and comorbidities. Similarly, the generalizability of the BPaLM/BPaL regimen's success rates may be constrained by variations in local healthcare infrastructure and patient demographics. These limitations emphasize the need for implementation research tailored to specific epidemiological and health system contexts.

Future research should prioritize several understudied areas. First, there is a need for longitudinal studies evaluating the durability of protection offered by the M72/AS01E vaccine, as well as its efficacy in immunocompromised populations, such as people living with HIV. Second, the role of host-directed therapies in combination with shorter regimens warrants investigation, particularly for patients with advanced disease or comorbid conditions [18-20]. Third, operational research is needed to identify the most effective delivery models for these innovations in resource-limited settings, including the potential role of public-private partnerships and community engagement. Finally, the ethical dimensions of deploying high-cost technologies in low-income countries must be addressed to ensure equitable access and avoid further marginalization of vulnerable populations.

The integration of these advancements into global TB control efforts will require coordinated action across multiple stakeholders, including researchers, policymakers, and healthcare providers [21,22]. While the scientific progress is undeniable, its ultimate impact will depend on the ability of health systems to adapt and deliver these tools to those who need them most. The findings from this study provide a roadmap for this transition, but their success will hinge on sustained political commitment, adequate financing, and a patient-centered approach to implementation.

Conclusion

This study underscores the transformative potential of recent innovations in tuberculosis control, demonstrating how advancements in diagnostics, treatment, and prevention collectively address critical gaps in the global elimination agenda. The integration of rapid molecular diagnostics, shorter all-oral regimens, and an efficacious vaccine candidate marks a pivotal shift in the TB landscape, offering tangible solutions to longstanding challenges such as diagnostic delays, treatment adherence, and transmission prevention. These findings not only validate the feasibility of accelerated progress toward the 2030 targets but also highlight the importance of precision medicine and tailored public health strategies in diverse epidemiological settings.

Looking ahead, the successful translation of these innovations into policy and practice will require addressing persistent systemic barriers, including health infrastructure limitations and equitable access to emerging technologies. Future research should prioritize implementation science to optimize delivery models, particularly in high-burden regions, while exploring complementary strategies such as host-directed therapies and combination prevention approaches. The convergence of biomedical and public health advancements presented here provides a robust foundation for TB elimination, yet sustained commitment to health system strengthening and global collaboration remains imperative to realize their full impact.

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