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Evaluating the Cost-Effectiveness of Short-Course Oral Regimens for Rifampicin-Resistant Tuberculosis

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Abstract

Treatment options for rifampicin-resistant tuberculosis (RR-TB) remain limited, with existing regimens frequently prolonged and associated with poor tolerability. In light of emerging data from the TB-PRACTECAL trial, nations are evaluating the programmatic implementation of 6-month, fully oral regimens. A Markov model was employed to assess the incremental cost-effectiveness of three bedaquiline-, pretomanid-, and linezolid-based regimens (BPaL, with or without moxifloxacin [BPaLM] or clofazimine [BPaLC]) relative to the prevailing combination of longer and shorter standard-of-care (SOC) approaches for managing RR-TB, adopting the healthcare provider perspective in India, Georgia, the Philippines, and South Africa. Total costs (in 2019 USD) and disability-adjusted life years (DALYs) were projected over a 20-year horizon, applying a 3% discount rate in the base-case analysis. Univariate and probabilistic sensitivity analyses were conducted to address parameter uncertainty. Results indicated that all three regimens enhanced health outcomes while lowering costs compared to the existing mix of prolonged and abbreviated SOC protocols across the four countries. The BPaL regimen emerged as the most cost-saving option overall, yielding per-person savings of $112 to $1,173. At a willingness-to-pay threshold of 0.5 times GDP per capita per averted DALY, BPaLM was identified as the optimal choice in every setting. These results suggest that regimens built on BPaL are highly likely to be both cost-saving and more efficacious than current standards across diverse contexts. Nations should prioritize the programmatic adoption of BPaL-based treatments.

Keywords: Tuberculosis, Rifampicin, Oral regimens, Infectious diseases

Introduction

Tuberculosis (TB) continues to be a leading global killer, second only to COVID-19 among infectious diseases [1]. In 2020 alone, approximately 9.8 million people developed active TB, resulting in 1.5 million deaths [2]. Of these cases, nearly 470,000 each year involve strains resistant to rifampicin (RR-TB), a cornerstone of first-line TB therapy [2]. RR-TB, which may coincide with resistance to isoniazid (MDR-TB) or fluoroquinolones (pre-XDR TB), has limited treatment options. Even with recent improvements, available regimens are long, complex, often require injections, and are associated with suboptimal outcomes—the global treatment success rate for RR-TB was only 59% in 2018 [2, 3].

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Recent developments have introduced shorter, all-oral treatment options. Regimens containing bedaquiline, pretomanid, and linezolid (BPaL) can be completed in six months, compared with the 9-month or 20-month regimens commonly used today. Pretomanid has received approval from the US FDA, the European Medicines Agency, and 28 additional countries, and is prequalified by the WHO [4]. Following evidence from the Nix-TB study, which demonstrated strong outcomes six months post-treatment in patients with highly drug-resistant TB (including treatment-intolerant MDR-TB and pre-XDR TB), the WHO recommended BPaL regimens for operational research in 2021 [5, 6]. While some adverse events related to linezolid were observed, the ZeNix trial showed that reducing linezolid to 600 mg daily maintained high treatment success while lowering toxicity [7].

The TB-PRACTECAL trial has provided further evidence supporting these shortened regimens. As the first multi-country, randomized, controlled phase II/III study to examine bedaquiline- and pretomanid-containing regimens in patients with pulmonary RR-TB, it was stopped early after all three experimental arms outperformed the control [8]. This trial included a diverse patient population, including individuals with fluoroquinolone-resistant TB and HIV co-infection.

In response to these advances and the potential to reduce treatment burden for both health systems and patients, WHO is preparing guidance for programmatic use of BPaL-based regimens, and countries are evaluating their potential cost and health impact [9]. A cost-effectiveness study of TB-PRACTECAL regimens implemented by Médecins Sans Frontières in South Africa, Belarus, and Uzbekistan is ongoing, with data collection in progress [10]. Policymakers require information not only on clinical efficacy but also on the likely economic value of these regimens in real-world programmatic settings. This analysis aims to estimate the incremental cost-effectiveness of the three TB-PRACTECAL regimens compared with current WHO-recommended RR-TB treatments across multiple countries.

Materials and Methods

We applied a Markov modeling approach to evaluate the additional cost-effectiveness of the three BPaL-based regimens tested in the TB-PRACTECAL trial for managing rifampicin-resistant TB, comparing them with existing standard-of-care treatments in India, Georgia, South Africa, and the Philippines **(Table 1).**

Table 1. Country characteristics.

Feature	India	South Africa	Philippines	Georgia	Source
GDP per capita in 2019 (USD)	6,998	13,010	9,292	15,623	[11]
Status of regulatory approval for pretomanid in BPaL regimens	Approved	Submission in progress	Submission in progress	Approved	[4]
Main short-course standard of care (SOC) regimens	Various 4-month regimens including combinations of Lfx, Cfz, Z, E, Hh, Eto/Pto, Bdq (6 months), etc.	5-month: Lfx, Cfz, Z, E	5-month: Lfx, Lzd, Cfz, Z, E	5-month: Mfx, Cfz, Z, E	[12–15]
Main long-course standard of care (SOC) regimens	18–20 months: Lfx, Lzd, Cfz, Cs, Bdq (6 months)	18–20 months: Lfx, Trd, Lzd, Cfz, Bdq (6 months)	18–20 months: Lfx, Lzd, Cfz, Bdq (6 months)	18–20 months: Lfx, Lzd, Cfz, Bdq (6 months)	[12–15]
Total individuals with rifampicin-resistant TB (RR-TB)	49,945	10,233	5,952	284	[2]
Percentage of tested TB patients who are HIV-positive	2.7%	58%	1.2%	1.8%	[2]
Proportion of RR-TB patients on short vs. long SOC regimens (current mix)	96% short / 4% long	74% short / 26% long	99% short / 1% long	31% short / 69% long	[2]
Treatment success rate in 2019 cohort	57.5%	64.8%	67.9%	69.4%	[2]
Death rate in 2019 treatment cohort	15.0%	17.6%	9.7%	6.0%	[2]

Treatment failure rate in 2019 cohort	12.8%	2.4%	1.8%	9.1%	[2]
Lost to follow-up rate in 2019 cohort	14.7%	13.9%	20.6%	11.6%	[2]
TB treatment coverage percentage	82%	58%	68%	73%	[2]

SOC, standard of care; GDP, gross domestic product; USD, United States dollars; Bdq, bedaquiline; Cfz, clofazimine; HIV, human immunodeficiency virus; Lfx, levofloxacin; Z, pyrazinamide; E, ethambutol; Hh, high-dose isoniazid; Eto, ethionamide; Pto, prothionamide; Trd, terizidone; RR-TB, rifampicin-resistant tuberculosis; Am, amikacin.

The modeling exercise estimated incremental costs from the healthcare provider's viewpoint, along with disability-adjusted life years (DALYs) prevented, across a 20-year time frame. This model-based evaluation was performed to address emerging policy issues that arose after the early conclusion of the TB-PRACTECAL trial and the subsequent WHO guidelines endorsing the programmatic implementation of BPaL-based regimens [9]. The approaches used for the economic assessment were modified from the originally planned per-protocol economic evaluation [10]. As this analysis relied on previously published data within a modeling framework, it did not necessitate ethical review or approval.

Patient and public involvement

This research was mainly aimed at policymakers, with the study question stemming from the Resource Considerations component required during the WHO guideline formulation process. Conducting an economic assessment is viewed as essential for crafting public health recommendations, and this investigation addressed that requirement. Although patients did not participate in designing this modeling study, the components related to clinical results were developed and carried out with substantial input from patient communities [16]. Study findings will be disseminated to community advisory boards in an accessible lay summary and shared in clinics at the trial sites. The compensation structure for participants in the primary trial was established through close consultation and received approval from relevant local ethics committees.

Study population and settings

Models were constructed to simulate the programmatic implementation of each treatment regimen across all individuals diagnosed with rifampicin-resistant TB (RR-TB) in four countries. These countries were selected for their diverse features that could influence broader global policy decisions, such as the prevalence of multidrug-resistant/rifampicin-resistant TB (MDR/RR-TB), the rate of HIV co-infection among TB patients, and the existing proportion of short versus long standard-of-care (SOC) regimens for MDR-TB. Key characteristics of each country are presented in **Table 1.**

Interventions and comparators

The TB-PRACTECAL trial assessed three regimens lasting six months: Arm 3 consisted of bedaquiline, pretomanid, and linezolid with a dose reduction (600 mg daily for 16 weeks, followed by 300 mg daily for the final 8 weeks) (BPaL). Arm 1 added moxifloxacin (400 mg) to the BPaL foundation (BPaLM); Arm 2 added clofazimine (50–100 mg) to the BPaL foundation (BPaLC). Every regimen from TB-PRACTECAL was evaluated against the prevailing combination of SOC regimens, derived from the proportions of patients placed on short versus long MDR-TB treatments as reported in the data supporting the latest Global TB Report [2]. Details of the short and long SOC regimens were based on the national guidelines for MDR-TB treatment in each country [12–15].

Model overview

A Markov state-transition model was constructed to track how a group of patients advances through different health conditions and events linked to each therapy approach. Individuals started the simulation with confirmed active rifampicin-resistant TB (RR-TB) upon beginning treatment. The typical starting age was fixed at 35 years, matching the average age seen among those enrolled in the TB-PRACTECAL study [17]. Every month, patients might advance to the following treatment month, drop out (loss to follow-up), fail therapy, or pass away.

The length of treatment varied by regimen: BPaL-inclusive standardised options were set at 24 weeks to align with the TB-PRACTECAL study design; typical short standard-of-care (SOC) options ran for 36 weeks; and extended SOC options extended to 80 weeks. Those who became lost to follow-up (LTFU) without finishing therapy had ongoing monthly opportunities to resume care within the initial two years after starting. Upon failing their first assigned regimen, every patient—irrespective of the starting option—was switched to an extended SOC "salvage" therapy. Anyone failing this salvage approach then progressed to a terminal "end-of-life" condition. Individuals achieving successful treatment completion carried a risk of relapse over the subsequent four years; the model excluded any reinfection possibilities. Those experiencing relapse could resume therapy in line with each country's reported TB treatment access rates. Potential reductions in TB transmission from briefer therapies were not incorporated.

Handling of treatment results

Model inputs for SOC regimen results drew from each country's officially reported 2019 cohort outcomes submitted to the WHO [2]. Risks of death or treatment failure were treated as comparable between short and long standardised SOC approaches [18]. Adopting methods from Walker *et al*. [19], the probability of loss to follow-up was allowed to change depending on duration already spent in treatment, with success probabilities adjusted downwards to capture the increased LTFU accumulation in prolonged SOC options.

Success rates for regimens tested in TB-PRACTECAL were derived per country by scaling the local SOC success figure using the observed relative likelihood of favourable outcomes at 72 weeks in the trial's experimental groups versus the control group. Data from the per-protocol analysis were selected for their greater caution. Success within the model meant avoiding all adverse events (such as LTFU, failure, relapse, or mortality) by the 72-week mark. Even though the trial indicated lower mortality in experimental groups, a cautious strategy assumed zero differences in death, failure, or relapse rates; any modelled gains in success were thus entirely credited to decreased LTFU. This restraint recognised that unusually low failure and mortality figures across trial groups might prove unrealistic under routine programme implementation, with relaxation of this constraint examined via one-way sensitivity testing.

Probabilities for monthly transitions across outcomes were computed according to the typical length of each therapy type. Both patient-related expenses and health consequences were summed across a 20-year lifetime perspective, employing monthly cycles. The 20-year span was deemed sufficient to include every significant cost and effect.

Effectiveness in the cost-effectiveness calculations was quantified as disability-adjusted life years (DALYs) prevented [20]. Recognising data on enduring health impairments after TB even among cured cases, the "post-TB" state received a disability weight of 0.053 [21]. When side-effect profiles lacked direct matches in the Global Burden of Disease listings, specialist input helped assign them to suitable proxy states. Overall disability weights for side-effect cases were derived via a multiplicative formula [22]. Base-case discounting of DALYs applied a 3% yearly rate [23].

Costs

Treatment costs were assessed from the healthcare provider's viewpoint, drawing on a blend of national MDR-TB treatment protocols, earlier published figures for service prices and utilization rates, and insights from specialists. This provider-focused approach was adopted owing to the scarcity of robust patient-side cost data across the studied nations. In Georgia, India, and the Philippines, the per-unit costs for outpatient appointments, hospital bed-days, community-based or additional visits, and diagnostic tests were taken from the Value TB dataset—the most comprehensive multinational TB costing research available [24]. For South Africa, costs of healthcare delivery, as well as those associated with interventions, medicines, and infusions for managing side effects, were obtained from published studies [25, 26]. Every cost figure is presented in 2019 US dollars. Prior USD amounts from earlier periods were adjusted upward using the US gross domestic product (GDP) deflator [11].

Monthly utilization rates for outpatient appointments, hospital bed-days, community or miscellaneous visits, and diagnostic tests were derived from the Value TB dataset, respective national protocols, and corroborated through specialist review [12, 15, 24]. Where feasible, the study applied actual service delivery volumes recorded in facilities during the Value TB project, which commonly varied from official protocols yet offered a truer picture of overall treatment expenses. These utilization figures were computed distinctly for the intensive and continuation stages of all standard-of-care (SOC) regimens, with a mandatory two-month hospitalization included for every regimen in Georgia. Service volumes per month under experimental regimens were taken to resemble those seen in the first six months of the abbreviated SOC regimen. Specialist input helped determine typical outpatient appointments and hospital bed-days needed per patient across various side effects. Individuals lost to follow-up (LTFU) were modeled as generating expenses for one monthly follow-up call or home visit until death or re-engagement with treatment.

Medication prices were retrieved from the Global Drug Facility Catalogue for each country [27]. Drug volumes were determined based on the prescribed SOC regimen in each nation, using standard adult doses for body weights of 51–70 kg. A 3% discount rate was applied to all costs in the primary analysis [23].

Handling of uncertainty and sensitivity testing

The primary analysis computed differences in costs and outcomes based on average values for all inputs. To evaluate uncertainty around these inputs, a probabilistic approach was employed, running 200 iterations while simultaneously drawing new values for every parameter. Success rate ratios followed a log-normal pattern in their variation, cost per unit drew from gamma distributions, and DALY disability weights used beta distributions.

Additionally, a deterministic one-way sensitivity analysis explored how results changed with individual alterations to critical inputs, including costs unrelated to medicines, market prices for bedaquiline and pretomanid, chances of patients returning after being lost to follow-up, the applied discount rate, and the utility assigned to life after TB. Extreme bounds were tested by cutting each of these inputs in half or doubling them when assessing the added costs and benefits of the new regimens.

Further scenario testing questioned the main assumption that better outcomes from the TB-PRACTECAL arms came mainly through fewer patients dropping out; separate runs instead attributed the same overall gain to lower mortality or reduced failure rates. No exploration of differences across subgroups or equity impacts was carried out, given that no subgroup breakdowns were available from these initial trial findings.

Funding source involvement

The TB-PRACTECAL study received complete funding from Médecins Sans Frontières (MSF). Sponsors from the funding organization contributed to reviewing and interpreting results, drafting the report, and approving submission for publication.

Results and Discussion

Table 2 summarizes the primary analysis. In every country studied, the ongoing blend of standard treatments proved to be the priciest choice, while the BPaL approach turned out to be the most affordable. Fully replacing the existing standard regimen mix with BPaL for everyone with MDR/RR-TB would deliver per-person savings from as high as $1,173 in South Africa down to $112 in India. Opting for BPaLM would cut expenses by $80 to $904 per individual and prevent between 0.7 and 1.3 DALYs for each patient treated.

Table 2. Base case results.

			Comparison with current SOC mix	
Country and regimen	**Total costs per person**	**Total DALYs per person**	**Incremental Costs Per Person**	**Incremental DALYs Averted Per Person**
Philippines				
Current SOC regimen mix (99% short, 1% long)	$1,329	5.4		
BPaL	$1,078	5.4	-$251	0.0
BPaLC	$1,174	5.3	-$155	0.1
BPaLM	$1,124	4.6	-$204	0.8
South Africa				
Current SOC regimen mix (74% short, 26% long)	$4,517	6.8		
BPaL	$3,344	6.6	-$1,173	0.2
BPaLC	$3,470	6.5	-$1,047	0.3
BPaLM	$3,520	6.0	-$997	0.8
India				
Current SOC regimen mix (96% short, 4% long)	$978	6.4		

BPaL	$867	6.4	-$112	0.0
BPaLC	$952	6.3	-$27	0.1
BPaLM	$899	5.7	-$80	0.7
Georgia				
Current SOC regimen mix (31% short, 69% long)	$4,211	4.7		
BPaL	$3,228	4.3	-$983	0.4
BPaLC	$3,327	4.2	-$883	0.6
BPaLM	$3,307	3.5	-$904	1.3

The standard of care (SOC) and disability-adjusted life years (DALYs) are referenced, with all costs expressed in 2019 US dollars.

Figure 1 illustrates the average lifetime costs across each cohort. Shortening treatment episodes with investigational regimens lowered non-pharmaceutical costs, with the most significant savings observed in South Africa and Georgia due to their higher visit-related expenses. In contrast, the reduction in non-pharmaceutical costs was smaller in India and the Philippines, where costs for non-tradeable inputs like personnel are relatively low and a larger proportion of patients already receive shorter SOC regimens. Costs for tradeable drugs were marginally higher with investigational regimens compared to short SOC regimens in all settings. Expenses related to adverse events and tracing patients lost to follow-up were generally greater under SOC regimens, though these differences had only a minor impact on overall costs.

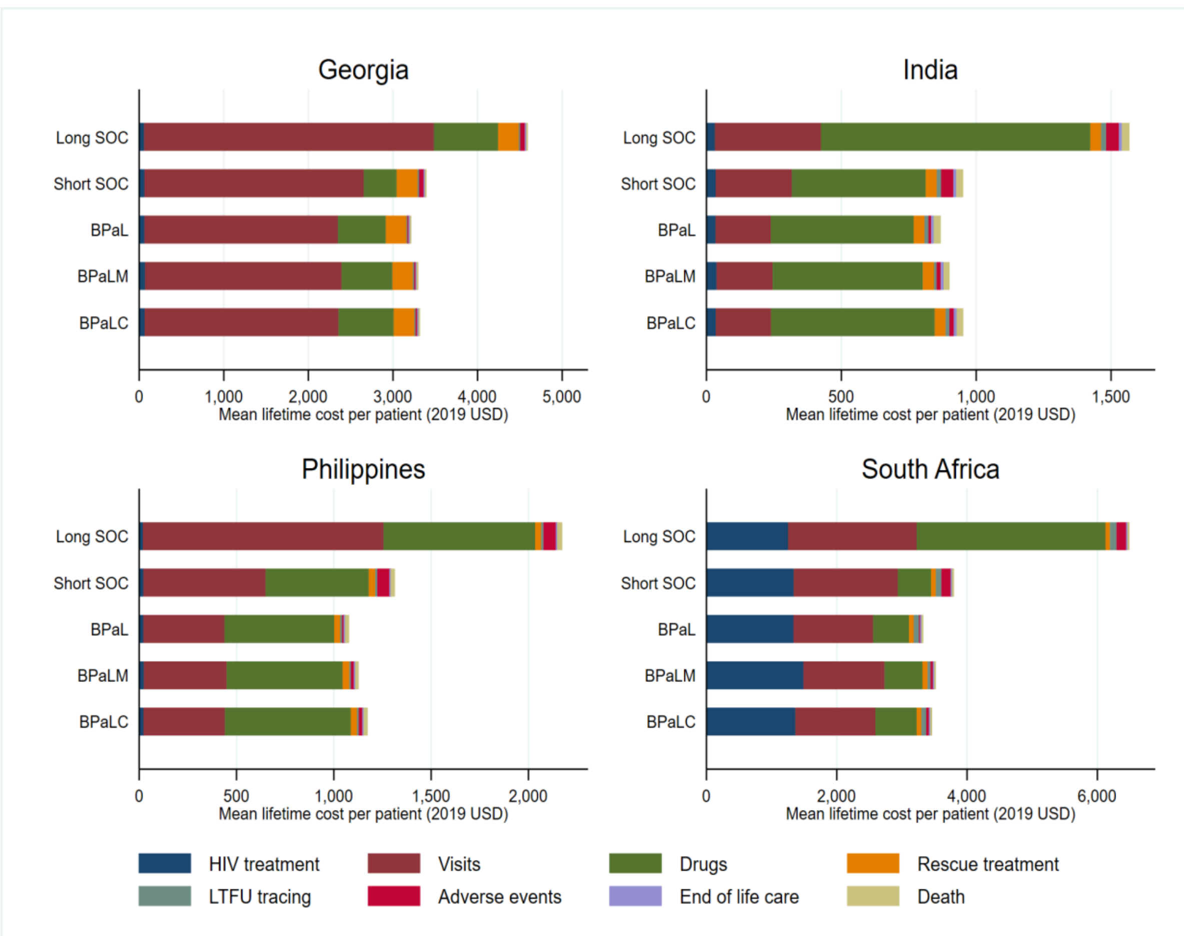

Figure 1. Displays the average lifetime costs broken down by country and treatment regimen.

In the probabilistic sensitivity analysis, all simulated scenarios demonstrated cost savings for the three investigational regimens in the South Africa, Philippines, and Georgia **(Figure 2)**. In India, the majority of simulations also indicated cost savings across regimens (99% for BPaL, 74% for BPaLC, and 94% for BPaLM). Across all countries, the average disability-adjusted life years (DALYs) averted over 200 simulations were positive for every regimen. Nevertheless, considerable uncertainty surrounded this outcome, particularly in the Philippines and India.

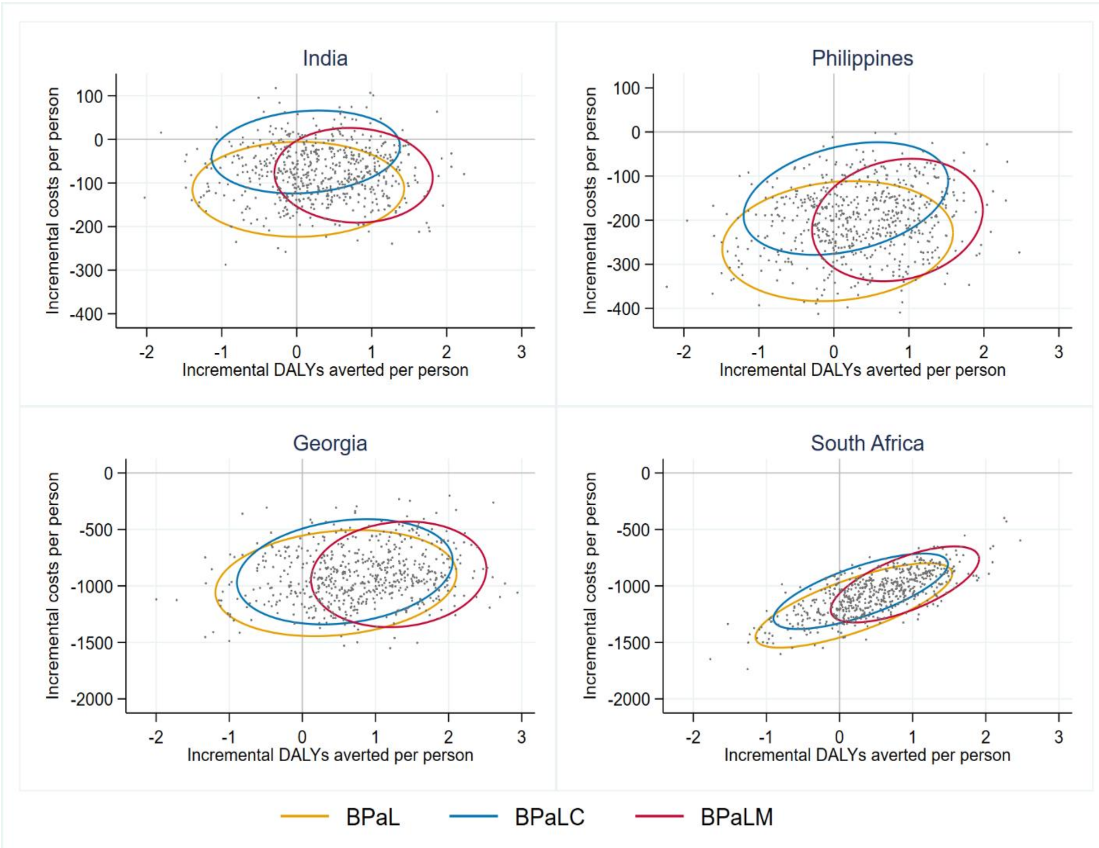

Figure 2. Probabilistic sensitivity analysis results

In our univariate sensitivity tests, the model's outcomes were most affected by non-drug costs in Georgia and South Africa, reflecting the relatively high cost of healthcare visits in these settings. Conversely, in India and the Philippines, where visit costs are lower, drug prices were the main driver of cost variation. Notably, in India—where the potential cost savings from investigational regimens were smallest—some parameter changes led to a modest increase in the incremental cost of these regimens compared to the existing SOC mix. Modelled health outcomes were particularly responsive to the discount rate, while adjustments to the post-TB DALY weight or the probability of patients returning after being lost to follow-up had little influence on overall results.

Figure 3 displays cost-effectiveness acceptability curves for the three investigational regimens alongside the current SOC mix across all countries. At a willingness-to-pay threshold of 0.5 times GDP per capita per DALY averted, BPaLM consistently emerged as the regimen with the highest probability of being cost-effective.

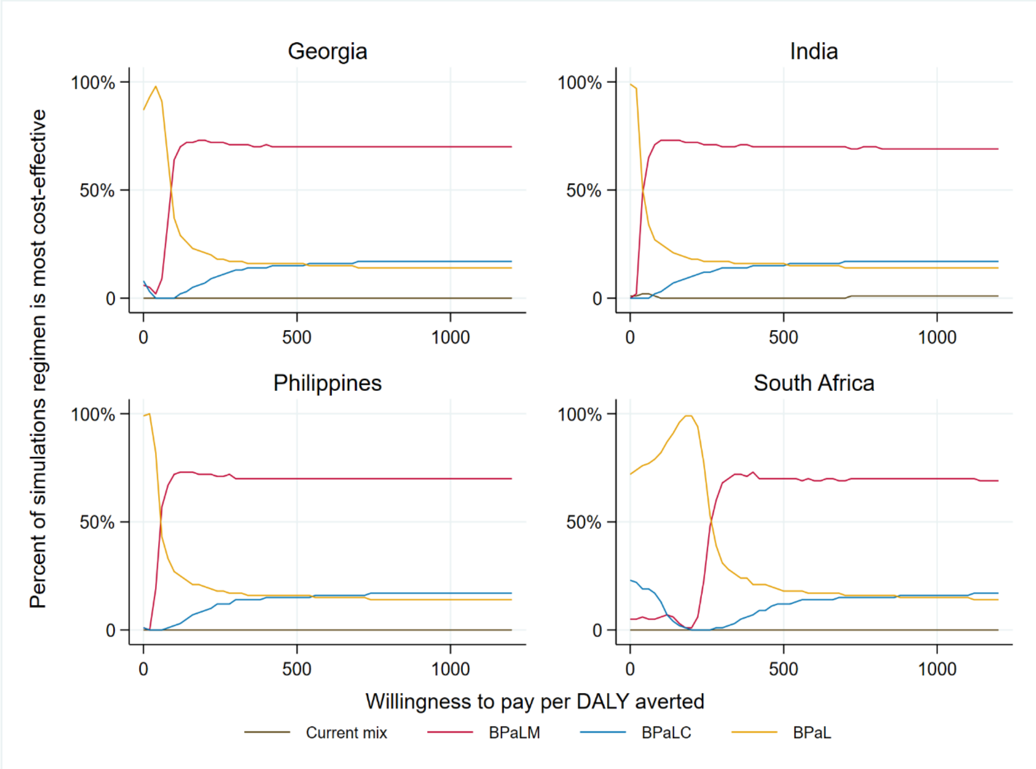

Figure 3. Curves showing the probability of cost-effectivenes..

We conducted a model-based analysis to estimate the incremental cost-effectiveness of implementing the BPaLM, BPaLC, and BPaL regimens at a programmatic scale compared with the current SOC mix in the Philippines, South Africa, Georgia, and India. Across all settings, our findings indicate that these regimens are highly likely to reduce costs. The base-case scenario was intentionally conservative, assuming no differences in mortality, treatment failure, or relapse compared with existing SOC regimens.

This study is the first to evaluate the cost-effectiveness of replacing the current standard of care with BPaL-based regimens for patients with RR-TB, regardless of fluoroquinolone resistance. Previous modeling studies have examined the economic and budgetary impact of BPaL in patients with pre-XDR TB or MDR-TB who are treatment-intolerant or non-responsive, using Nix trial data [28, 29]. Those studies reported that BPaL was cost-saving in South Africa, Georgia, and the Philippines, with results sensitive to drug pricing and assumptions regarding patient loss to follow-up [29]. In Indonesia, Kyrgyzstan, and Nigeria, the adoption of BPaL was projected to reduce XDR-TB-related expenditures by 15–32% of current costs [28]. Our results align with these conclusions and extend them to patients with rifampicin-resistant but fluoroquinolone-susceptible TB.

The main source of projected cost savings in our model was the reduction in non-drug costs due to shorter treatment durations. Realizing these savings depends on whether health systems can repurpose freed-up resources. For example, fewer TB visits may free clinician or nurse time for other services. If resources cannot be reallocated effectively, or if service efficiency declines due to excess capacity, the savings may not fully materialize.

Our analysis was limited to the provider perspective because of data availability, but the potential financial benefits for patients and households could be considerable. Worldwide, 87% of people with drug-resistant TB experience catastrophic TB-related expenses [2]. Shortened treatment courses could prevent or mitigate household impoverishment caused by TB.

It is important to note that our findings come from a modeling study and are intended to guide decision-making rather than serve as definitive evidence. Several limitations exist: the model did not separate RR-TB patients based on fluoroquinolone resistance, since TB-PRACTECAL outcomes were not reported separately.

The model also did not capture transmission dynamics or the potential development of resistance to new drugs in BPaL-based regimens. We assumed full replacement of current SOC with BPaL regimens, which may not be feasible in practice due to resistance patterns, drug intolerance, or procurement constraints. Evidence gaps remain for specific groups such as pregnant women, children under 15, and patients with TB meningitis.

Conclusion

Recent evidence consistently indicates that six-month bedaquiline-based regimens are likely to generate cost savings at current drug prices. Adopting these regimens at a programmatic level could not only enhance treatment success for RR-TB but also free up resources that could be redirected to other priorities within TB programs. As countries consider transitioning to shorter, fully oral regimens, it is essential for TB programs to plan how to best utilize these potential savings. Strategic investments—such as strengthening patient support to reduce loss to follow-up, expanding TB case-finding initiatives, or enhancing TB prevention in high HIV-prevalence settings—could accelerate progress toward End TB targets and bring us closer to eliminating TB globally.

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Ethics Statement: None

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