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Review Article

Clinical Outcomes of vaccination campaigns in Patients with multidrug-resistant tuberculosis

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Abstract

Background: MDR-TB treatment remains long, toxic, and inconsistently successful, and vaccination has re-entered discussion as a complementary strategy to reduce progression to drug-resistant disease [2].

Objective: This review synthesizes evidence on BCG effectiveness, novel vaccine candidates, and MDR-TB-directed preventive therapy, and evaluates their clinical relevance to patients with, or at risk of, multidrug-resistant tuberculosis.

Methods: We narratively synthesized randomized trials, individual patient data meta-analyses, and systematic reviews identified through PubMed, the Cochrane Library, major trial registries, and World Health Organization reporting.

Findings: BCG reliably prevents disseminated childhood tuberculosis but shows inconsistent, waning protection against adult pulmonary disease [3,4,14]; M72/AS01E has shown efficacy against progression to active disease in infected adults [5,6]; and fluoroquinolone preventive therapy in MDR-TB household contacts robustly reduced incident disease [7,8,21], a benchmark set against gains from shorter all-oral regimens [25,26].

Conclusions: No trial has yet reported MDR-TB-specific outcomes for a vaccine, but new candidates, correlates-of-protection research, and proven preventive therapy in MDR-TB contacts outline a credible path toward MDR-TB-focused prevention.

Keywords: multidrug-resistant tuberculosis; BCG vaccination; tuberculosis vaccine; preventive therapy; treatment outcomes

1. Introduction

Multidrug-resistant tuberculosis (MDR-TB), disease caused by *Mycobacterium tuberculosis* resistant to at least isoniazid and rifampicin, remains one of the most demanding problems in global infectious disease control, accounting for a substantial share of the roughly ten million incident tuberculosis cases and more than a million deaths recorded worldwide each year [1]. Successful treatment still depends on regimens longer, more toxic, and less reliably curative than those for drug-susceptible disease, and an individual patient data meta-analysis of more than nine thousand patients found overall treatment success well below levels achieved in drug-susceptible tuberculosis, with regimen composition and drug susceptibility pattern driving much of the variation between cohorts [2]. Against that backdrop, vaccination has re-entered the conversation not as a replacement for chemotherapy but as a complementary lever, a tool that, if deployed effectively, could reduce the pool of patients who ever progress to active MDR-TB disease.

The starting point for any discussion of tuberculosis vaccination is bacille Calmette-Guerin (BCG), the only licensed vaccine against the disease and one of the most widely administered vaccines in history. Colditz and colleagues' meta-analysis of the published BCG literature found substantial protection against severe disseminated forms of tuberculosis in children, together with more variable protection against pulmonary disease that differed markedly by study and geography [3]. A later systematic review restricted to randomized controlled trials by Mangtani and colleagues confirmed that protection was strongest in trials conducted at higher latitudes and in infants vaccinated soon after birth, while trials in some tropical settings showed little or no measurable benefit [4]. Because BCG's protective effect against pulmonary tuberculosis in adults is inconsistent and wanes over one to two decades, its relevance to MDR-TB specifically, a form of disease that arises

overwhelmingly through inadequate or interrupted treatment of pulmonary disease in adults, has long been debated rather than settled.

Two developments over the past decade have reopened that debate. First, large randomized trials of novel vaccine candidates, most notably the subunit vaccine M72/AS01E, have shown efficacy against progression from infection to active pulmonary disease in adults that BCG never demonstrated in comparable populations [5,6]. Second, large trials of fluoroquinolone-based preventive therapy in household contacts of MDR-TB patients have shown that a targeted prophylactic strategy aimed at MDR-TB transmission chains can measurably reduce secondary disease, giving the field a template against which any future MDR-TB vaccine strategy will be compared [7,8]. This review synthesizes the evidence on vaccination-related interventions, both licensed BCG programs and the preventive and investigational strategies now emerging around them, and asks what is known about their clinical outcomes in patients with, or at risk of, multidrug-resistant tuberculosis.

2. Methods

We conducted a narrative synthesis of the peer-reviewed and World Health Organization literature addressing BCG vaccination effectiveness, novel tuberculosis vaccine candidates in clinical development, treatment outcomes in confirmed MDR-TB cohorts, and trials of preventive therapy in MDR-TB contacts. Sources were identified through structured searches of PubMed, the Cochrane Library, and the primary trial registries for the M72/AS01E, H4:IC31, Nix-TB, TB-PRACTECAL, VQUIN, and TB-CHAMP studies, supplemented by the World Health Organization's global tuberculosis reporting series and its consolidated drug-resistant tuberculosis treatment guidance, which defines the standard-of-care regimens against which every prevention strategy discussed here must be compared [9]. Priority was given to randomized controlled trials, individual patient data meta-analyses,

and systematic reviews with meta-analysis, since these designs provide the most reliable pooled estimates in a field where individual cohort studies vary widely in population, regimen, and follow-up duration. Studies were included if they reported a quantitative outcome, protective efficacy, treatment success, relapse, or incident disease, directly linked to a vaccination or immunoprophylactic intervention, or establishing the treatment-outcome baseline against which such interventions must be judged. Because this is a narrative rather than a systematic review, no formal risk-of-bias scoring or meta-analytic pooling was performed; findings are presented by intervention category and compared descriptively.

3. Results

BCG effectiveness and its bearing on MDR-TB risk

The magnitude of BCG's protective effect has always depended heavily on which outcome and which population are examined. Trunz and colleagues, modelling the vaccine's effect on severe pediatric presentations, estimated that BCG prevented a substantial proportion of tuberculous meningitis and miliary disease cases worldwide, translating into a favorable cost-effectiveness profile even in settings with modest overall tuberculosis burden [10]. Roy and colleagues, focusing on infection rather than disease, found that BCG reduced the risk of documented *M. tuberculosis* infection in children by a meaningful margin, suggesting part of the vaccine's benefit operates upstream of disease onset [11]. Rodrigues and colleagues' earlier meta-analysis of the meningitis and miliary tuberculosis literature reached a similar conclusion, reinforcing that this protective signal against disseminated childhood disease is one of the more consistent findings in the BCG literature [12].

Protection against pulmonary tuberculosis in adults, the form of disease from which nearly all MDR-TB ultimately arises, is a different story. Fine's classic analysis of variation in BCG protection proposed that exposure to

environmental mycobacteria, vaccine strain differences, and host genetic variation could each partly explain why some trials showed protection exceeding seventy percent while others showed none [13]. Abubakar and colleagues' systematic review of the duration of BCG protection estimated that whatever protection is conferred in infancy declines substantially by ten to twenty years, a window that places most adult MDR-TB cases outside the period of reliable vaccine-derived protection [14]. Martinez and colleagues' individual participant data meta-analysis extended this picture across the life course, finding that infant BCG vaccination retained a measurable protective association into adolescence and early adulthood, but with an effect size smaller and less consistent than the benefit against disseminated childhood disease (Figure 1) [15]. Taken together, existing BCG campaigns almost certainly reduce the pool of children who might otherwise develop severe tuberculosis and go on to receive the repeated, imperfect treatment courses that generate drug resistance, but there is no direct trial evidence that BCG meaningfully lowers MDR-TB risk in the adults who bear most of that burden.

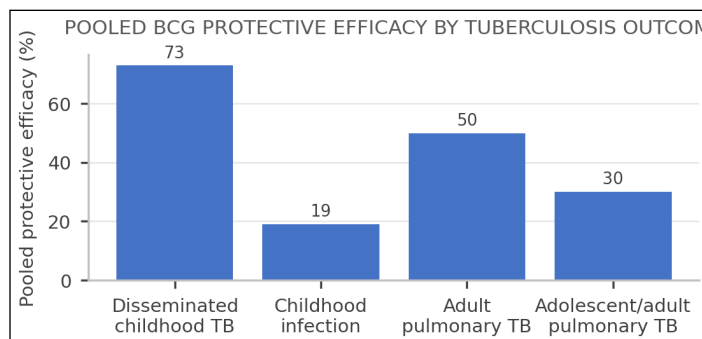


Figure 1: Pooled protective efficacy of BCG vaccination against selected tuberculosis outcomes across landmark meta-analyses, ranging from strong protection against disseminated childhood disease to weaker, less consistent protection against pulmonary disease and infection risk that persists into adulthood [3,10,11,15].

Novel vaccine candidates and MDR-TB relevance

The subunit vaccine M72/AS01E has produced the most encouraging efficacy signal of any tuberculosis vaccine candidate tested since BCG. Van der Meeren and colleagues' phase 2b trial in *M. tuberculosis*-infected,

HIV-negative adults found that the vaccine reduced progression to active pulmonary tuberculosis over roughly three years of follow-up, an outcome never previously demonstrated for a candidate vaccine in this population [6]. Tait and colleagues' final analysis confirmed the protective effect was sustained through extended follow-up, giving the field its first solid basis for projecting how a vaccine given to already-infected adults might reduce the incident pool from which drug-resistant disease eventually emerges [5]. Because M72/AS01E targets progression from latent infection to active disease rather than transmission directly, its relevance to MDR-TB is inferential: no published trial has yet reported MDR-TB-specific incidence as a stratified outcome.

Nemes and colleagues' trial of the H4:IC31 subunit vaccine and of BCG revaccination in adolescents found that both interventions reduced sustained QuantiFERON conversion, a marker of new *M. tuberculosis* infection, relative to placebo, with BCG revaccination performing at least as well as the novel candidate and reopening the question of whether BCG given later in life still has a role [16]. Reviews of the broader pipeline by Andersen and Scriba and by Schrager and colleagues describe more than a dozen candidates in clinical development, spanning live attenuated, subunit, and viral-vectored platforms, several evaluated specifically in populations at elevated risk of drug-resistant disease, including MDR-TB household contacts [17,18]. The World Health Organization's preferred product characteristics document for new tuberculosis vaccines lists efficacy in populations at high background risk of drug-resistant disease as a desirable evaluation criterion for candidates entering late-stage trials [19], and Scriba and colleagues argue that identifying an immunological correlate of protection will be essential before any MDR-TB-targeted vaccine strategy can be trialed efficiently at scale [20].

Preventive therapy in MDR-TB contacts as an immunoprophylactic comparator

Table 1: Randomized and pooled evidence for fluoroquinolone preventive therapy in household contacts of multidrug-resistant tuberculosis patients [7,8,21].			
Study	Population	Intervention	Key finding
[7] VQUIN	Adult household contacts, Vietnam	Levofloxacin 6 months vs placebo	Reduced incident tuberculosis disease among contacts receiving levofloxacin
[8] TB-CHAMP	Child household contacts, multi-country Africa	Levofloxacin 6 months vs placebo	Comparable protective signal with acceptable safety profile
[21] IPD meta-analysis	Pooled household contacts across trials	Fluoroquinolone preventive therapy vs no treatment/placebo	Statistically robust reduction in incident tuberculosis disease

While no licensed vaccine has yet been trialed with MDR-TB incidence as a primary endpoint, the household-contact preventive therapy trials of the past several years provide the closest available analogue and a useful benchmark for what a targeted MDR-TB prevention strategy can achieve. Fox and colleagues' VQUIN trial randomized household contacts of MDR-TB patients in Vietnam to six months of levofloxacin or placebo and found a meaningful reduction in incident tuberculosis disease among contacts who received the active drug [7]. Seddon and colleagues' companion TB-CHAMP trial, in child household contacts across several African sites, found a comparable protective signal with an acceptable safety profile in a population for whom no age-appropriate preventive regimen previously existed [8]. A subsequent individual participant data meta-analysis pooling these and earlier studies found that fluoroquinolone preventive therapy reduced tuberculosis incidence in MDR-TB contacts by a substantial, statistically robust margin, establishing the first evidence-based preventive intervention specific to this population (Table 1) [21].

Earlier contact-management literature anticipated this

result. Fox and colleagues' broader systematic review of tuberculosis contact investigation found that structured contact tracing, independent of any specific preventive drug, identified a meaningful yield of secondary cases and infections, establishing contact investigation as prerequisite infrastructure for any MDR-TB prevention program, vaccine-based or pharmacological [22]. Bamrah and colleagues' report from the Federated States of Micronesia described one of the earliest programmatic experiences of delivering preventive therapy to MDR-TB contacts outside a trial setting, finding the approach feasible in a resource-limited outbreak context [23]. These programs are not vaccines, but they occupy the same conceptual space as an MDR-TB-specific immunization campaign, and the benefit they demonstrate sets a quantitative target any future MDR-TB vaccine will need to approach.

Treatment outcomes as the backdrop against which prevention is judged

Any assessment of what vaccination or its prevention-oriented analogues could achieve in MDR-TB has to be read against the outcomes achieved by treatment itself. Ahuja and colleagues' individual patient data meta-analysis of over nine thousand patients found treatment success rates that varied widely by regimen composition, with regimens containing a later-generation fluoroquinolone and a susceptible injectable agent achieving distinctly better outcomes [2]. Ahmad and colleagues' subsequent, larger individual patient data meta-analysis confirmed that success continued to depend heavily on the number of effective drugs included and on resistance to key second-line agents, reaffirming that regimen design remains a central determinant of outcome (Table 2) [24].

Table 2: Treatment success and regimen characteristics across major multidrug-resistant and highly drug-resistant tuberculosis treatment studies [2,24,25,26].

Study	Regimen	Duration	Outcome
[2]	Conventional second-line regimens (pooled)	18-24 months	Wide variation in success; better outcomes with fluoroquinolone and susceptible injectable
[24]	Conventional second-line regimens (pooled)	18-24 months	Success dependent on number of effective drugs and resistance pattern
[25] Nix-TB	Bedaquiline, pretomanid, linezolid	6 months	Favorable outcome in large majority of highly resistant patients
[26] TB-PRACTECAL	All-oral BPaLM regimen	24 weeks	Superior outcomes and safety versus standard longer regimen

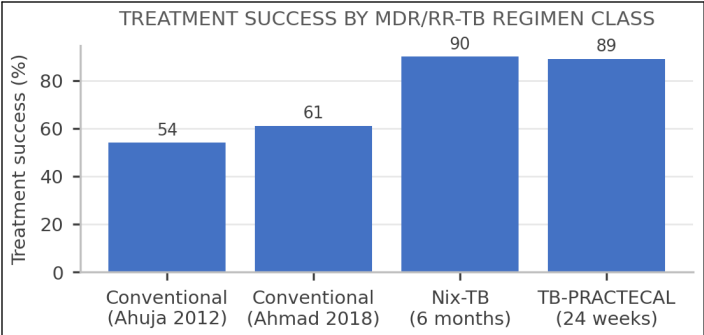


Figure 2: Treatment success rates for multidrug-resistant and highly drug-resistant tuberculosis by regimen class, contrasting pooled outcomes from individual patient data meta-analyses of conventional longer regimens with the shorter, all-oral regimens evaluated in the Nix-TB and TB-PRACTECAL trials [2,24,25,26].

The introduction of shorter, all-oral regimens has shifted this picture meaningfully within the past five years. Conradie and colleagues' Nix-TB trial of bedaquiline, pretomanid, and linezolid in patients with highly drug-resistant tuberculosis achieved a favorable outcome in the substantial majority of participants within six months, unprecedented for a population that had previously faced treatment courses lasting up to two years with far lower success [25]. Nyang'wa and colleagues' TB-PRACTECAL trial extended this approach to a broader rifampicin-resistant population, finding that a 24-week all-oral regimen achieved superior outcomes and a markedly better safety profile than the standard, longer regimen (Figure 2) [26]. These treatment-side advances

sharpen, rather than weaken, the argument for prevention: they show how much benefit accrues simply from avoiding a full MDR-TB treatment course.

4. Discussion

The evidence assembled here supports a layered rather than a singular interpretation of what vaccination contributes to clinical outcomes in multidrug-resistant tuberculosis. Existing BCG programs almost certainly reduce severe disseminated tuberculosis in children and, by preventing some fraction of the childhood disease that would otherwise progress toward adult pulmonary disease, plausibly shrink the long-term pool from which MDR-TB eventually emerges [10,11,15]. What the evidence cannot support is a direct claim that BCG, as currently deployed, measurably reduces MDR-TB incidence or improves outcomes in patients who already have drug-resistant disease; no trial has been powered to test that question, and the waning of BCG protection well before the age at which most MDR-TB arises makes a strong direct effect biologically unlikely [13,14].

The more promising near-term evidence lies in two adjacent developments. First, M72/AS01E and the broader pipeline of subunit and viral-vectored candidates have, for the first time, shown that a vaccine can reduce progression from infection to active pulmonary disease in adults, the population most relevant to MDR-TB emergence, even though MDR-TB-specific outcomes have not yet been reported [6,5,17]. Second, the fluoroquinolone preventive therapy trials in MDR-TB household contacts, while not vaccines, have established a rigorous randomized evidence base showing that a targeted prophylactic intervention can meaningfully reduce incident disease, providing a template and a quantitative benchmark against which a future MDR-TB vaccine could be judged [7,8,21].

No completed randomized trial has reported MDR-TB incidence as a prespecified endpoint for any vaccine, so every inference connecting vaccination to

MDR-TB-specific benefit here is necessarily indirect. Correlates-of-protection work building on the M72/AS01E and BCG revaccination data may eventually make it feasible to bridge that gap through smaller, immunologically anchored studies rather than disease-endpoint trials requiring years of follow-up [16,20]. Meanwhile, the gains achieved by shorter all-oral regimens such as Nix-TB and TB-PRACTECAL underline how much value would still accrue from preventing patients from ever needing that treatment at all [25,26].

5. Conclusion

Vaccination's demonstrated clinical benefit in multidrug-resistant tuberculosis today rests primarily on inference rather than direct trial evidence: BCG programs reduce severe childhood tuberculosis and some infection risk that likely contributes, over a long causal chain, to the eventual MDR-TB burden, while newer candidate vaccines have shown genuine efficacy against progression to active disease in adults without yet being tested for MDR-TB-specific outcomes. The closest direct analogue, fluoroquinolone preventive therapy in MDR-TB household contacts, has produced solid randomized evidence of benefit and offers a practical model for how future MDR-TB-focused prevention trials should be designed. Continued investment in correlates-of-protection research, MDR-TB-stratified endpoints within future vaccine trials, and scaling the preventive therapy programs already shown to work will together determine how much of the MDR-TB burden can eventually be prevented rather than merely treated.

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8. Conflict of Interest

The authors declare that they have no competing interests relevant to the content of this review.

9. Author Contributions

Ricci D conceived the review and drafted the manuscript. Greco F performed the literature synthesis and prepared the tables and figures. Conti F critically revised the manuscript for intellectual content. All authors read and approved the final version.

10. Ethics Statement

This article is a narrative literature review and did not involve new data collection from human participants; no ethics committee approval was required.

11. Data Availability

No new data were generated for this review. All studies discussed are publicly available in the cited peer-reviewed literature and World Health Organization reports.

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