

Next Generation Market Shaping Strategic Initiative

Improving access to new quality TB screening and diagnostics tools

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This document summarizes key information on the Global Fund to Fight AIDS, Tuberculosis and Malaria's initiative to improve access to new quality tuberculosis (TB) screening and diagnostic tools through market-shaping approaches for TB diagnostics and treatments. It includes information on the current context, the Global Fund market shaping approach and support provided to countries.

Background

Finding and treating people with TB continues to be the most challenging aspect of the TB care cascade. In 2023, nearly 25% of the estimated people with TB were undiagnosed.¹ The current tools available for TB diagnosis either have limited sensitivity and specificity (microscopy) or have high capital and infrastructural requirements (molecular diagnostics).

Only 44% of the estimated drug-resistant TB patients in 2023 were notified,² underscoring a critical gap in access to molecular diagnostics and sensitivity testing. In addition, while WHO recommends using rapid molecular diagnostic assays as initial tests in adults and children, many country programs continue to rely on smear microscopy as the initial test, with only 48% of TB patients who received a molecular test at time of diagnosis.³ These diagnostic gaps are even more critical in vulnerable groups, including children and some people living with HIV for whom production of sputum is difficult.

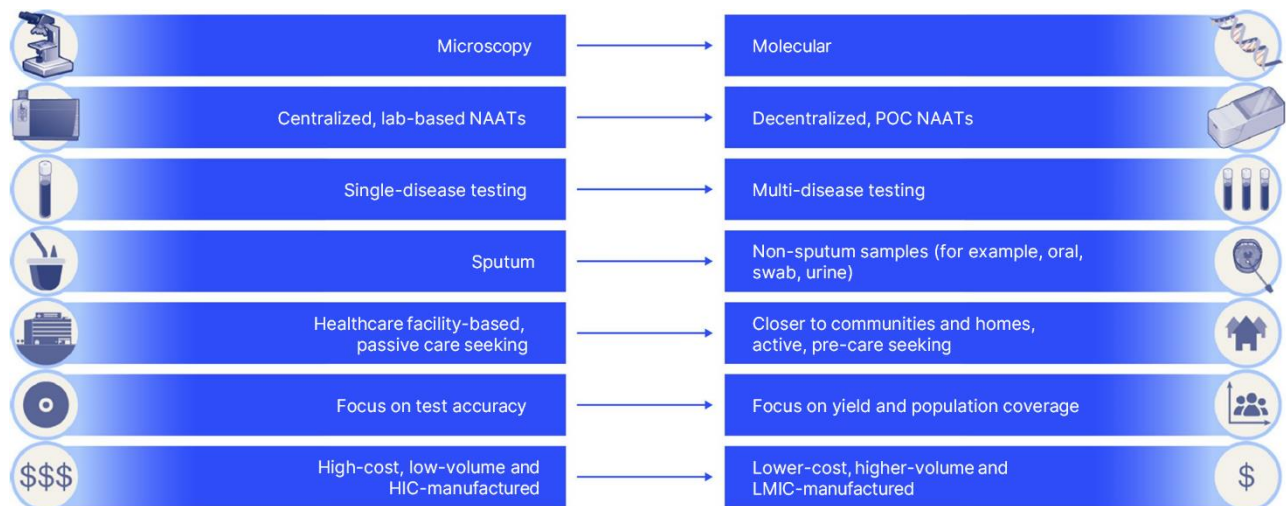
¹ WHO Global Tuberculosis Report 2024, <https://www.who.int/publications/i/item/9789240101531>

² Idem

³ Idem

Early and accurate diagnosis is critical to reach the End TB targets. Figure 1 highlights some of the investments in diagnostics that are critical to achieve these targets. The introduction of new manufacturers and technologies in the TB diagnostic market will require concerted efforts including, but not limited to, appropriate market shaping interventions.

Figure 1. Seven transitions that can transform how tuberculosis is diagnosed and close the diagnostic gap.



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Source: Pai et al, Nature Microbiology, 2023: <https://www.nature.com/articles/s41564-023-01365-3>

Over the past two decades, the Global Fund partnership has played a critical role in shaping markets to support the targets set out in the Sustainable Development Goals 3 (SDG3) for health and well-being for all, including tackling HIV, TB and malaria by 2030. Each year, over US\$2 billion from country grants are used to procure health products, including antiretroviral medicines (ARVs), artemisinin-based combination therapies, long-lasting insecticidal nets, TB medicines and diagnostic products. The Global Fund will continue to work across the partnership to improve access to existing screening and diagnostic tools.

The Global Fund Market Shaping Approach

Through the Global Fund Pooled Procurement Mechanism (PPM) serving more than 83 countries, the Global Fund is using its buying power to encourage manufacturers to meet global quality requirements, secure increased supply capacity for low- and middle-income countries and lower health product prices, contributing to efficient and effective implementation of country programs. These efforts have contributed to the partnership saving 65 million lives since 2002.

This work is expanding with the Next Generation Market Shaping Strategic Initiative,⁴ providing funding opportunities for health product introduction, and capacity building for local manufacturing and in-country supply chain and procurement. The strategic initiative is based on [the NextGen Market Shaping Approach](#) which aims to support the delivery of [Global Fund Strategy 2023-2028](#) and drive equitable access to quality-assured health products.

Market shaping for tuberculosis screening, diagnostic and treatment tools

In 2023, Global Fund market-shaping efforts resulted in significant price reductions for key commodities, enabling governments to expand interventions and invest in other critical areas. Working with partners, prices were reduced by 20% for TB diagnostic test cartridges, by 30% for the short-course TB preventive treatment known as 3HP and by 55% for bedaquiline, the main treatment for drug-resistant TB.

Building on years of experience, the Global Fund is intensifying the efforts to actively monitor the pipeline of TB products and prepare for new tools entering the market, in close collaboration with technical partners, donor agencies, manufacturers and other stakeholders. For the current Grant Cycle 7 (GC7), those efforts will focus on products closest to market entry, which include new screening and diagnostic tools (see Figure 2). The Global Fund will also continue to monitor and evaluate products for market-shaping support as new treatment or prevention products become available.

Figure 2. Products in the immediate tuberculosis diagnostic pipeline for GC7

| Urinary point-of-care tests | New sampling techniques with near point-of-care tests | Low complexity diagnostics |
|--|--|--|
| <ul style="list-style-type: none"> • Third generation lipoarabinomannan (LAM) tests in trials. • Larger market if indication broadens to outside people living with HIV. | <ul style="list-style-type: none"> • Tongue swabs. • Potentially very large market, depending on the indication. • Use in new near point-of-care platforms. | <ul style="list-style-type: none"> • Multi-disease platforms • Similar space as GeneXpert and TrueNat. • Additional competition to market with potential lower prices and better service and maintenance. |

Source: The Global Fund

⁴ Strategic initiatives support the success of country allocations through programs that cannot be funded through country grants.

To improve access to new quality TB screening and diagnostic tools, the Global Fund will support:

- **Market size estimation:** work with partners to define the market size, particularly for near point-of-care tests that can be decentralized to primary health care and community levels, and any additional multi-disease low complexity nucleic acid amplification test (NAAT) platforms (similar to GeneXpert and TrueNat).
- **Demand generation:** facilitate regional platforms for knowledge sharing to support country readiness activities, including potential demand generation and implementation planning.
- **Technical assistance:** provide technical support for in-country planning and implementation, as required.

Looking Ahead

Through the NextGen Market Shaping Strategic Initiative, the Global Fund will continue to work with partners to reduce barriers to health product availability and affordability, improve the responsiveness and timeliness of health product service and delivery, and promote resilient and sustainable supply chains. Strengthening the whole value chain across health product markets for known diseases, from research and development to the last mile delivery, will enhance the global and national readiness to deliver critically needed products.