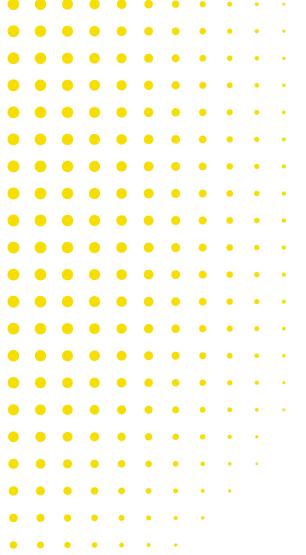


# The TB Quarterly Update Innovations

JANUARY/FEBRUARY 2025





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### **About the TB Quarterly Update**

The TB Quarterly Update is produced by the TB team at the Global Fund to share best practices, lessons learned and information from countries supported by the Global Fund, partners and other stakeholders, as well as updates on new innovations and tools coming onto market. If you have any information you would like to share, please reach out to TBQuarterlyUpdate@theglobalfund.org.

### 1. What's New

## The African Society for Laboratory Medicine Special Convention on Diagnostics 2024

From 4 to 7 November 2024, the African Society for Laboratory Medicine (ASLM) held a special convention on diagnostics in Abidjan, Côte d'Ivoire. ASLM and the Global Fund, through the NextGen Market Shaping Strategic Initiative, brought together stakeholders for a dedicated session to discuss the implementation of new TB diagnostic tools, focusing on near point-of-care (NPOC) tests and tongue swab sampling techniques. The main objectives of the meeting were to gather insights on planning for these tools, refine market estimation efforts and understand the data required to support country planning and diagnostic algorithm updates. Key takeaways included:

Accessibility and patient-centered testing:
 Stakeholders emphasize the importance of accessible diagnostics, particularly in decentralized settings, such as community and primary healthcare facilities. These tools can reduce the need for long-distance travel for patients and empower community health workers with simplified technology. One of the key benefits of swab-based testing is its suitability

- for patients who cannot produce sputum, such as children and people living with HIV. Additionally, swab-based testing supports rapid, same day test-and-treat approaches. The integration of these tests into broader healthcare programs also creates opportunities to mobilize community health workers and involve multiple health programs in TB testing.
- Implementation challenges: Potential barriers to implementation include: (a) technical performance concerns, such as potential sensitivity and specificity limitations, which could lead to missed cases and the need for retesting; (b) navigating policy changes and securing stakeholder buy-in; (c) resource and infrastructure constraints, including financial resources, human capacity, and sustainable supply chain systems; and (d) ensuring quality assurance and documentation requirements at different sites.
- Enablers for successful implementation: To support implementation planning, stakeholders emphasize the need for regulatory and evidence requirements, such as WHO prequalification and national registration, along with robust evidence demonstrating effectiveness in decentralized settings. Validation processes, including national verification studies and pilot programs, are essential





to optimize implementation strategies. Integration into national strategic plans and diagnostic algorithms is crucial, as is securing adequate funding, developing comprehensive training programs and establishing quality assurance systems. Engaging civil society organizations early and developing clear implementation guidelines for all stakeholders are also vital for successful deployment.

Simultaneous advances in decentralizing case management: The discussions also highlighted the importance of simultaneous evolution in diagnostics and case management to avoid gaps between diagnosis and treatment initiation. While there are challenges to overcome, the benefits of these new diagnostic tools are significant. By addressing these challenges through careful planning, stakeholder engagement and continuous quality evaluation, the implementation of NPOC and swab testing can greatly enhance TB diagnostic capabilities and improve patient outcomes in resource-limited settings.

### **Stop TB Partnership Board Meeting 2024**

The Stop TB Partnership (Stop TB) held its 38th annual board meeting from 12 to 14 December 2024 in Abuja, Nigeria. The meeting provided a platform for governments, TB survivors, communities, civil society, researchers, innovators and others to learn more about innovative TB interventions and Stop TB's advocacy

priorities in 2025. Sessions explored a range of emerging evidence on TB stigma, TB vaccines, TB nutrition, and TB innovations, which all address the needs of hard-to-reach populations, household contacts, and others.

The week-long event also included a high-level political leadership meeting co-hosted by the First Lady of Nigeria and an African High-Level Dialogue on TB financing co-hosted by the African Union and the Stop TB Partnership, the Nigeria TB 2024 International Conference and the Africa Parliamentarians High-Level Summit. Discussions from the week highlighted the need to secure increased resources for TB interventions, tools and research and urged leaders of TB high-burden countries to increase funding for the TB response. More information about the annual meeting is available at the Stop TB website.

### WHO asymptomatic TB update

Interest in asymptomatic TB has increased in recent years, due to a growing emphasis on screening and earlier diagnosis. Individuals with asymptomatic, pulmonary, and bacteriologically confirmed TB are likely to contribute substantively to TB transmission and the global burden of TB disease, even if they have minimal or no cough. Analysis of data from 14 countries in Africa and Asia suggests that about two thirds of global TB transmission may be from

individuals with asymptomatic TB. In October 2024, the WHO consulted national TB program staff, civil society and technical and funding agencies to develop a definition of asymptomatic TB. Their objective is to identify research gaps and set priorities that are critical for WHO guidance and relevant for TB programs and research. As a result of this consultation, asymptomatic TB was defined, split into bacteriologically confirmed

and unconfirmed, and resulted in subsets of current WHO definitions. The WHO included a new section on the definitions of asymptomatic TB in the latest WHO Global Tuberculosis Report and have planned to disseminate the definitions for programs to use. They have also developed guidance on operationalization of the definitions. More information is available at the WHO website.

**Table 1:** Definitions of asymptomatic TB following a WHO consultation 2024 (compared with the current TB definitions according to the latest WHO guidance)

Source: The WHO

Current WHO definitions of TB	Definitions of asymptomatic TB
TB disease: A person with disease caused by the M. tuberculosis complex.	Asymptomatic TB:  A person with TB disease who did not report symptoms suggestive of TB during screening.
Bacteriologically confirmed TB:  A person from whom a biological specimen is positive by a WHO-recommended rapid diagnostic test, culture or smear microscopy.	Asymptomatic TB, bacteriologically confirmed: A person with bacteriologically confirmed TB who did not report symptoms suggestive of TB during screening.
Clinically diagnosed TB:  A person who does not fulfil the criteria for bacteriological confirmation but has been diagnosed with TB disease by a medical practitioner who has decided to give the person a full course of TB treatment. This definition includes pulmonary cases diagnosed based on radiographic abnormalities and extrapulmonary cases diagnosed based on suggestive clinical presentation or histology. Clinically diagnosed cases subsequently found to be bacteriologically positive (before or after starting treatment) should be reclassified as bacteriologically confirmed.	Asymptomatic TB, bacteriologically unconfirmed:  A person with bacteriologically unconfirmed TB who did not report symptoms suggestive of TB during screening.  Of note: given the use of the term "bacteriologically unconfirmed" in the definition of asymptomatic TB, the term "clinically diagnosed" will be replaced with "bacteriologically unconfirmed" in future editions of WHO products and publications.

### **New price reductions in key TB drugs**

Record price reductions were announced in February 2025 for lifesaving TB drugs. The new price for bedaquiline is US\$90 per treatment course for the Lupin and Macleods products. The price of the six-month bedaquiline, pretomanid, linezolid and

moxifloxacin (BPaLM) regimen is now US\$364. These price reductions translate to lower costs for nearly every WHO-recommended DR-TB regimen, bringing significant savings to national TB programs worldwide. More information is available at the <a href="Stop TB website">Stop TB website</a>.

# 2. Knowledge Sharing and Learning Resources

### Case study: Implementing tuberculosis preventive therapy in India

### **Background**

India bears the largest TB burden in the world and one-third of its population is estimated to have TB infection (TBI). Apart from accurate early diagnosis and treatment, preventing community transmission by addressing TB infection is critical to reduce TB incidence. Tuberculosis preventive therapy (TPT) is considered a key intervention in accelerating the decline in TB incidence and achieving India's TB elimination goals. In 2021, India's National TB Elimination Programme (NTEP) prioritized the programmatic management of TBI to roll-out and scale up TPT based on the programmatic management of TB preventive treatment (PMTPT) guidelines. The Clinton Foundation, the Union and FIND implemented large-scale TPT initiatives across various states in India under the guidance of the NTEP, and were supported by the Global Fund's grant implemented from 2021 to 2024.

### Implementation

The Axshya Plus project, implemented by the Union and the Joint Effort for Elimination of TB 2.0 (JEET) project, led by the Clinton Foundation and FIND, focused on TBI management. Interventions were rolled out in 208 districts across 23 states in India between 2021 and 2024. Implementation was undertaken in collaboration with seven partners: TB Alert India, Centre for Health Research and Innovation, World Vision, Catholic Health Association of India, German Leprosy and TB Relief Association – India, Karnataka Health Promotion Trust, and Alert India.

The project was aligned with India's PMTPT guidelines and focused on the management of TBI through early screening and provisioning of TPT to all household contacts of index pulmonary TB patients. Activities included doorstop TB screening for household contacts of pulmonary TB patients at their homes and medical evaluations to assess for contraindications and rule out

active TB. The project then initiated TPT with adherence support for eligible household contacts (i.e., who were identified to not have active TB), provided patient education and counselling, and facilitated adverse event management, when necessary.

Two project models were used for this project:

- The test and treat model involved using interferon gamma-release assays (IGRA) for diagnosing TBI in household contacts (aged 5+ years) and initiating TPT based on positive results. End-to-end IGRA services were provided with sample collection through a phlebotomist at the homes of household contacts.
- The treat only model did not involve tests. Household contacts were instead directly initiated on TPT based on eligibility.

Primarily, the project used two TPT regimens—daily isoniazid for six months (6H) for most household contacts and a weekly rifapentine-isoniazid regimen for three months (3HP) in a few districts, mainly those with the "test and treat" model. Workshops and continued medical education sessions were conducted to raise awareness and improve TPT uptake, especially for private sector engagement. Providers were sensitized to use diagnostics like chest X-ray and IGRA tests. Efforts were also made to engage private healthcare providers to support TB symptom screening and TPT initiation among household contacts of patients who were treated in the private sector. The project also enabled follow-up visits and phone calls to monitor adherence, manage adverse events and ensure treatment completion.

Two methods were used for data recording. The first one involved an integrated application developed under the project to record TB symptom screening, TPT initiation, adherence and outcomes, with regular validation and updates communicated to the NTEP. The second method consisted of direct data recording and integration within the NTEP's Ni-kshay platform (National TB Surveillance System), which supported comprehensive data collection and analysis.





#### **Results**

Over 800,000 drug-sensitive TB patients were notified during the project. About 95% of the notified patients were able to successful stay connected via tele-calling. This was attributed to two major enablers: (i) steady improvement in data quality reported on Ni-kshay through feedback to NTEP teams; and (ii) coordination with NTEP staff at sub-district level, which enabled reach-out to patients with incorrect or no mobile numbers and addresses in the Ni-kshay system.

Since the start of the project, roughly 3.16 million household contacts have been found eligible for screening. Approximately 90% of these were screened for TB symptoms by field staff. Of this number, 79% were eligible for TPT after a medical evaluation. Overall, over 1.29 million people were initiated on TPT, with a completion rate of 80% of household contacts. The project led to an additional yield of over 3,500 TB cases who had undergone X-ray or other tests to rule out active TB (>60% of TB diagnosis from asymptomatic individuals).

The project introduced several innovative approaches to enhance the effectiveness of TPT delivery, including:

- Integrated data systems: The use of a dedicated data application allowed for streamlined data collection and management. Ultimately, the project data was integrated into Ni-kshay, ensuring that it was appropriately represented on the national surveillance portal.
- **Tele/video-consultation:** Pilots like tele/video consultation in areas with limited access to healthcare

facilities helped reduce transportation barriers and improved follow-up rates.

 Private sector engagement: Targeted workshops and continuing medical education improved engagement with private healthcare providers, enhancing uptake of TPT services among household contacts of private sector-treated TB patients.

#### Lessons learned and next steps

The project faced various challenges, leading to important lessons for future TB control efforts. These included the following:

- Service delivery: Observations indicated that the chances of initiating TPT for household contacts were better when they were approached earlier, preferably within a month of treatment initiation of the index patient. Additionally, the uptake of TPT was higher when a shorter regimen was provided and any diagnostics were performed before TPT initiation.
- Supply chain management: Shortage of and delays in the receipt of isoniazid (INH) supplies, particularly the 6H regimen, disrupted TPT initiation in several states. Effective planning and coordination with NTEP were crucial to overcoming these challenges.
- TB infection positivity: TB infection positivity varied across the country and was dependent upon the type of TBI testing. IGRA positivity resembled close to the output of national prevalence survey.
- Cost of IGRA testing: While IGRA testing helped avoid unnecessary TPT, its high cost (US\$29 per test) limited its scalability. The need for more costeffective testing methods was evident.
- Importance of counselling: High-quality counselling

in the early stages of TPT initiation significantly influenced adherence rates, particularly in addressing stigma and increasing understanding of TPT among household contacts. Specific communication strategies targeting behavior change for a spectrum of stakeholders (i.e., patients, providers and healthcare workers) remained essential.

 Follow-up post TPT completion: The project teams supported household contacts until the TPT treatment was completed. However, long term follow-up is required to assess the effectiveness of the regimens.

The collaborative efforts under the JEET and Axshya Plus projects significantly contributed to expanding TPT in India. The integration of house-to-house service delivery, innovative data management and continuous stakeholder engagement in both public and private sectors were key drivers of their success. As India progresses towards achieving its TB-free goal, the experiences and lessons learned from addressing TBI will serve as a valuable blueprint for similar efforts worldwide.

### Case study: Scaling up tuberculosis preventive therapy (TPT) in Zimbabwe

#### **Background**

The implementation of programmatic management of TB preventive therapy (TPT) in Zimbabwe involves a comprehensive package of interventions. These interventions include identifying and testing individuals who need to be screened, providing effective and safe TPT with little to no risk of adverse events, and conducting monitoring and evaluation throughout the process. In 2020, Zimbabwe adopted and introduced shorter regimens for TPT, specifically the 3HP and 3RH regimens, to align with WHO recommendations. To ensure patients receive the full course of TPT and improve treatment outcomes, TPT medicines are now dispensed as a complete course rather than in partial doses.

#### **Implementation**

With support from the Global Fund, the Ministry of Health and Child Care developed a TPT acceleration and surge plan to scale up TPT across the country and achieve 100% coverage among people living with HIV by the end of 2023. The project developed TPT targets at sub-national levels, disseminated them to all health facilities, and completed trainings for relevant health care workers. To support effective monitoring and evaluation of TPT implementation, the project revised existing TPT data collection tools to enable better tracking of progress and outcomes related to TPT administration throughout Zimbabwe. Specific activities included:

- Collaboration and integration of HIV/TB activities: Collaboration was strengthened among various national programs and the supply chain management system to ensure seamless service delivery and resource allocation. The project also conducted research focused on TPT to identify best practices and outcomes. Partnerships between national programs and implementing partners were established to enhance the reach and effectiveness of TPT initiatives, maximizing the impact of TB prevention strategies across communities and ensuring that vulnerable populations received adequate care.
- TB interventions related to TPT: Key interventions included the implementation of TB screening protocols at every home visit from a health care worker, particularly for individuals accessing HIV services, with an emphasis on reaching children living with HIV. Contacts of TB patients were systematically assessed for their eligibility for TPT. Once identified, eligible individuals were provided with a 6-month regimen of isoniazid (6H).
- Household child contact evaluation: Household contacts aged 0-14 years of TB patients were evaluated at local health facilities or within community

settings. The aim was to identify children at risk and ensure they received appropriate preventive care. Through the Global Fund, 220 motorcycles were procured to support contact investigation. For children identified as vulnerable, a three-month daily regimen of isoniazid and rifampicin (3RH) was provided, using child friendly formulations to improve adherence and treatment outcomes.

The Unitaid-supported IMPACT4TB (I4TB) initiative promoted the transition to a short, effective regimen of 3HP as the preferred TPT option for people living with HIV. This included individuals who are stable on antiretroviral therapy (ART), those who are not fully informed on ART, and household contacts. The goal was to fully implement these strategies by August 2022, to enhance TB prevention in the context of HIV care.

### **Innovations**

The Ministry of Health and Child Care in Zimbabwe used the following innovative strategies to enhance patient care, improve treatment adherence and ultimately reduce the burden of TB and HIV in the populations served.

- Comprehensive screening for TB and HIV: Incorporated a dual screening process that allows the simultaneous identification of TB and HIV in patients.
- Simultaneous initiation of ART and TPT: Enabled the initiation of ART and TPT on the same day.
- Streamlined timing for TPT after ART initiation: Minimized the time taken to start TPT after initiating ART.
- Integration of TPT activities into ART differentiated service delivery models: Grafted TPT activities within existing ART differentiated service delivery models, making TPT more accessible and streamlining service delivery.
- Routine TB screening for people living with HIV: Identified and managed TB cases early for people living with HIV, reducing transmission and improving patient health.
- Engagement of community health workers and hybrid contact investigation: Supported community health workers in outreach, education, and follow-up, helping to bridge the gap between healthcare providers and patients. Worked collaboratively with environmental health technicians to track household TB contacts.
- **Use of telehealth approaches for TPT follow-up:** Enabled greater flexibility and access to care, particularly in remote or underserved areas, while also ensuring patients received ongoing support.
- Integration of research findings into implementation: Informed implementation stages with evidence-based research findings.
- A feasibility study of the 3HP regimen: Assessed the viability and effectiveness of 3HP treatment regimen in 20 healthcare facilities as part of the IMPACT4TB project, which served as a critical starting point for the introduction of this regimen.

#### Results

The management of TPT in Zimbabwe started in 2012 with just ten demonstration sites aimed at testing and refining the approach. Over the following decade, remarkable growth and transformation was achieved, eventually scaling to more than 95% of health facilities across the nation by 2022. In parallel, the expansion of ART sites providing isoniazid preventive therapy (IPT) has been significant. In 2012, only 10 out of 1,560 ART sites (less than 1%) offered IPT. By December 2021, this number soared to 1,610 out of 1,648 ART sites. Additionally, the number of people living with HIV who are on ART and started IPT increased exponentially, from just 98 individuals in 2012 to 929,446 by December 2021. Figures 1 and 2 show the exponential growth in TPT coverage in PLHIV over the years.

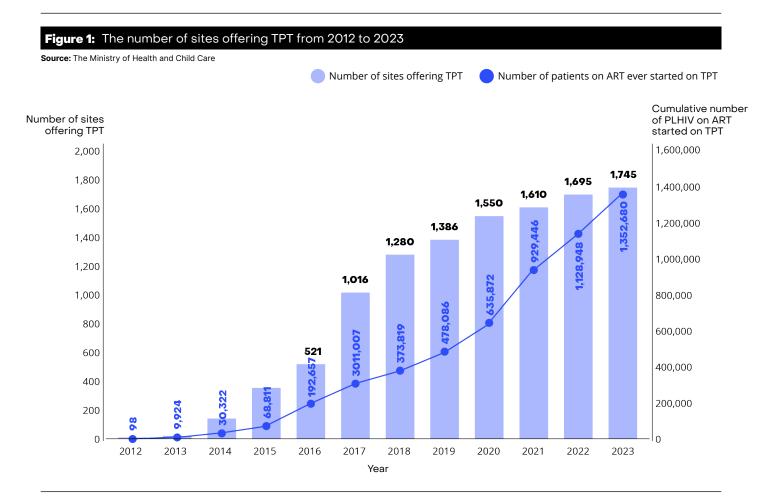
In addition, the number of contacts screened for TB increased by 124% from January to June 2022 compared to the same period in 2024 (see Figure 3). From January to June 2024, a total of 10,699 TB contacts were initiated on TPT, a significant rise from

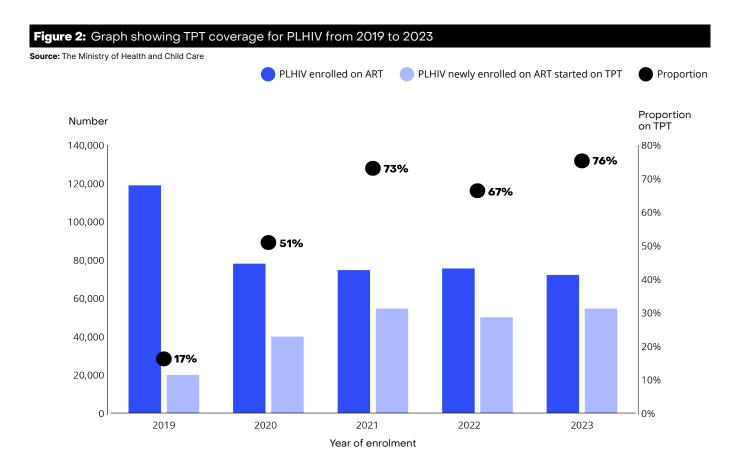
the 2,919 contacts initiated during the same period in 2022 (see Figure 3). This increase can be attributed to various factors, including:

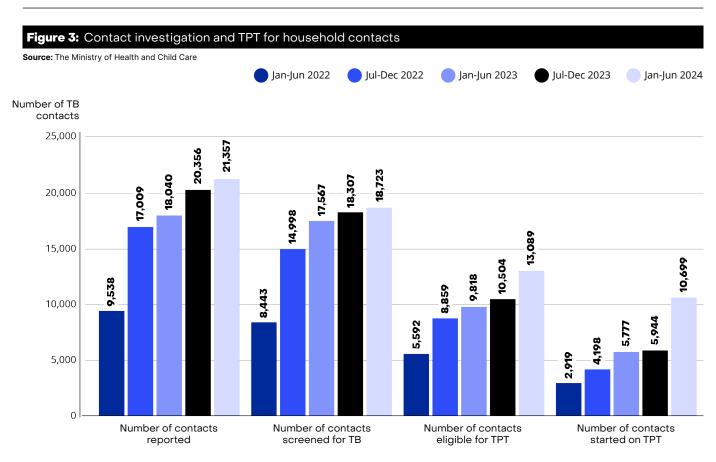
- Capacity-building efforts on TPT and contact investigation in 2022.
- · The introduction of shorter TPT regimens.
- The implementation of demand creation approaches.
- Additional resources provided through the Global Fund TB recovery plan support.
- The deliberate prioritization of contact investigation and TPT in the support and supervisory visits conducted by the program in 2023 and 2024.

Implementation challenges included:

- Inadequate investments in recording and reporting, along with limited implementation of electronic health record systems.
- Unclear roles and involvement of the private sector in the implementation of TPT.
- Insufficient capacity of health facility laboratories to conduct tests for drug adverse events.







#### Lessons learned and next steps

Scaling up TPT in Zimbabwe highlighted lessons learned when rolling out a package of TB treatment interventions. These include:

- It is crucial to invest in household contact evaluation to support TPT initiation and scale up of TPT in the future.
- To avoid artificial and real shortages of 3HP, relationships with all stakeholders should be strengthened and commodities should be managed efficiently.
- Tele-health should be used systematically to enhance treatment adherence and timely management of adverse events.
- 4. Community involvement is key to sustain uptake and scale up of shorter TPT regimens across all target population.
- Capacity building efforts should be holistic and tailored to needs of the health care worker, community health workers, clients and the local context.
- Involving the Ministry of Health at all levels is important to promote ownership and accountability of TPT implementation using 3RH.
- Strengthening monitoring and evaluation is crucial. Catalyzing Pediatric Tuberculosis Innovations (CaPTB) introduced contact investigation and TPT registers for community-based contact evaluation and TB screening and referral.
- 8. Managing human resources is a key element for planning and TPT implementation.
- On-the-job mentorship proved to have better outcomes compared to short clinical attachment for training of health care workers.
- 10. It is important to sensitize caregivers and communities to generate demand and enhance acceptance of TPT. CaPTB developed targeted information, education

and communication for health care workers and communities, emphasizing the importance of early TB diagnosis and TPT among child contacts and adherence to TB treatment and TPT.

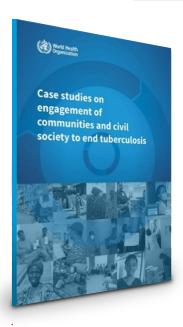
The Ministry of Health and Child Care of Zimbabwe has also identified the following next steps to enhance the scale up of TPT:

- Develop national policy on cascade of care for TB preventive treatment.
- 2. Strengthen human resources capacity.
- 3. Increase data driven support and mentorship.
- 4. Enhance domestic financing of TPT activities and consider including funding for TPT drugs through funding applications.
- Strengthen TB contact evaluation through incentives for village health workers; travel support for facility health staff, community health workers and family members of TB patients; and patient education.
- Strengthen monitoring and evaluation through systematic collection, analysis and reporting of data across the cascade of care for TPT shifting towards digital data capture (e.g. using WHO Prevent TB mobile application).
- Strengthen community engagement in TPT by providing investments to support for systematic engagement, training, provision of support and supervision and tools for community health workers.
- 8. Strengthen TPT adherence and mechanisms for management of drug adverse events.
- Ensure uninterrupted supplies by strengthening capacity and infrastructure for appropriate forecasting, quantification, supply planning, storage and distribution of TPT related commodities.
- 10. Generate demand through use of information, education and communication materials and outreach activities.

### 3. Other Updates

## WHO case studies on engagement of communities and civil society to end tuberculosis

Meaningful engagement of civil communities affected by TB is critical to improving the reach and sustainability of TB interventions. WHO recently published a collection of case studies showcasing various global, regional, and country-level experiences of civil society and community engagement in the efforts to end TB. The case studies highlight innovative approaches and best practices for engaging diverse stakeholders, including affected communities, governments and private sector, in policy development, resource mobilization and local action. Examples include piloting community action groups in Pakistan, providing mental health support to promote non-discrimination and raise awareness of stigma in Peru and piloting a TB screening app in Zambia. Designed to complement the WHO Guidance on engagement of communities and civil society to end tuberculosis, the collection provides practical examples of successful community and civil society collaboration in the TB response, aiming to inform and inspire national stakeholders in their efforts to end TB and promote people-centered care. The case studies can be on found the WHO website.



### The Conference on Innovations in Tuberculosis 2025

The Conference on Innovations in Tuberculosis will be held for a second time on 12 May 2025, in Windhoek, Namibia. It aims to shed light on innovations in TB diagnostics, challenges in the clinical management of TB in advanced HIV, and diverse perspectives on how to integrate care for TB, HIV and other concomitant conditions. The conference brings a timely debate on the future of drug resistance testing and current limitations to data-driven solutions for TB, among other relevant aspects. The program features plenary lectures, abstract presentations, a poster gallery, roundtable discussions, multiple networking opportunities and a lively exhibition hall. It provides an exceptional opportunity for earlycareer investigators to discuss their work with the globe's leading experts. Abstracts are invited in the following categories:

- Screening for symptomatic and/or asymptomatic TB
- TB-related comorbidities and coinfections
- · TB clinical management, including in advanced HIV
- · TB drug resistance
- TB diagnostics
- Post-TB lung disease
- Al and Big Data in TB research and/or program implementation

Given the important interplay between TB and HIV in Africa, the program will be organized as a pre-event to the annual INTEREST Conference on HIV research in resource-contains settings. More information on the conference can be found here.

### 4. Voices

TB remains a public health problem in Zimbabwe. Zimbabwe has developed policies and guidelines to ensure access to TB prevention services for high-risk groups. With Global Fund support, we have scaled up shorter TPT regimens for contacts, people living with HIV and people with silicosis, using innovations like the hybrid contact investigation model to enhance TB care and prevention.



**Dr. Fungai Kavenga**Deputy Director, TB Prevention and Control
Ministry of Health and Child Care, Zimbabwe

In the absence of a TB vaccine, TB preventive treatment is our strongest tool to break the chain of transmission. Investing in community-led initiatives, ensuring access to Al equipped digital X-rays and integrating prevention into primary health care is critical. Prioritizing prevention today protects future generations from this preventable, curable disease and brings us closer to ending TB.



**Sania Saeed** Stop TB Celebrity Ambassador, Pakistan





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### About the NextGen Market Shaping Strategic Initiative

The NextGen Market Shaping Strategic Initiative, financed by the Global Fund, will support the implementation of innovative approaches and mechanisms for the introduction and scale up of new tuberculosis tools in Global Fund-supported countries. This initiative is part of the Global Fund NextGen Market Shaping approach, which outlines a holistic set of interventions to shape innovation and accelerate new product introductions at scale, promote capacity building for regional manufacturing and drive environmentally sustainable procurement and supply chains.