INDIA TUBERCULOSIS ROADMAP OVERVIEW, FISCAL YEAR 2024

This is an overview of the USAID/India FY 2024 Tuberculosis (TB) Roadmap, implemented with the FY 2023 budget. The roadmap was developed in consultation with the National TB Elimination Program (NTEP) and with the participation of national and international partners involved in TB prevention and care in the country.

According to the World Health Organization (WHO), India's estimated TB incidence rate in 2022 was 199 per 100,000 population, translating to an estimated 2,820,000 incident cases. Of these, 2,255,64, or 80 percent, were notified to the NTP. In the same year, HIV-negative TB mortality was estimated at 23 per 100,000 population or 331,000 deaths. In 2022, only 33 percent of people with notified TB were tested with WHO-recommended rapid diagnostics at the time of diagnosis, and 64 percent were bacteriologically confirmed. A total of 52,029 people were diagnosed with RR/MDR-TB, and an additional 12,382 people were diagnosed with pre-XDR/XDR-TB. Among these people with DR-TB, 94 percent were put on treatment.

The National Strategic Plan (NSP) for TB Elimination in India 2017-2025 puts forward bold strategies with commensurate resources to rapidly decline TB in the country by 2025 that align with global End TB targets and Sustainable Development Goals to attain the vision of a TB-free India.

The prioritized set of actions for the NSP 2017-2025[1]:

The requirements for moving toward TB elimination were integrated into four strategic pillars: Detect, Treat, Prevent, and Build; the following priority set of actions are in the NSP 2017-2025:

Detect	Find all TB patients with or without drug resistance with an emphasis on reaching TB patients seeking care from private providers and undiagnosed TB in high-risk populations: - Scaling up free, high-sensitivity diagnostic tests and algorithms. - Scaling up effective private provider engagement approaches. - Universal testing for drug-resistant TB. - Systematic community screening of high-risk populations.

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[1] National Strategic Plan 2017-25 for TB Elimination in India.

Treat	Initiate and sustain all patients on appropriate anti-TB treatment wherever they seek care, with a patient-centric approach and social support: ● Preventing loss of TB cases in the cascade of care with support systems. ● Providing free TB drugs for all TB cases. ● Developing a universal daily regimen for TB cases and rapid scale-up of short-course regimens for drug-resistant TB and DST-guided treatment approaches. ● Adhering to person-centric monitoring and social support to sustain TB treatment. ● Eliminating catastrophic costs by linkages of eligible TB patients with social welfare schemes, including nutritional support.
Prevent	Prevent the emergence of TB in susceptible populations: ● Scaling up air-borne infection control measures at healthcare facilities. ● Treating TB infection in contact of bacteriologically confirmed cases. ● Addressing social determinants of TB through an intersectoral approach.
Build	Build and strengthen enabling policies, empowered institutions, and human resources with enhanced capacities and financial resources: ● Translating high-level political commitment to action through supportive policy and institutional structures. ● Restructuring program management structure through substantial human resource augmentation and reform. ● Employing multi-sectoral collaboration. ● Developing community response for TB elimination. ● Strengthening health systems and integrated TB services. ● Augmenting financial resources commensurate to the desired burden reduction.

The proposed FY 2023 USAID TB budget for India is $20 million. With this level of funding, USAID will support the following technical areas:

REACH

TB diagnosis

The National Strategic Plan advocates for early identification of presumptive TB cases at the first point of care in private or public sectors and prompt diagnosis using susceptible diagnostic tests to provide universal access to quality TB diagnosis, including drug-resistant TB in the country. The TB laboratory network has been expanded over the years to provide better access to quality-assured diagnostic services. USAID's main strategies and approaches to establish and maintain a comprehensive, high-quality TB diagnostic network and increase DR-TB case finding:

- Institutional strengthening of the public sector network of TB laboratories to improve quality and efficiencies of the TB diagnostics care cascade in NTEP.

- Demonstrating private sector lab engagement for TB diagnostic care cascade.

- Supporting the Central TB division in the design and implementation of research on new TB diagnostics and tools and evaluation of active case finding (ACF) strategies

- Demonstrating a model for strengthening sample collection and transport (SCT).

- Supporting Whole Genome Sequencing and DR-TB Surveillance.

- Developing artificial intelligence (AI) tools to improve diagnostic processes like cough-based TB screening tools, Line Probe Assay reading tools, X-ray reading and interpretation tools, etc.

- Increasing the use of appropriate diagnostic tools through interventions to strengthen functional specimen transport networks and quality laboratory management systems.

- Scaling up of rapid diagnostic tests and diagnostic monitoring tools.

- Improving pediatric TB case detection by capacity building of peripheral health facilities on pulmonary and extrapulmonary specimen collection procedures.

Engaging all care providers

In 2022, the private health sector notified 733,694 individuals with TB, the highest annual notifications from the private health sector under the NTEP, contributing to 30 percent of notifications. While there is an increasing trend in TB notifications from the private sector, service gaps in the private sector go against standards for care. USAID's main strategies and approaches to increase facility-based TB case finding:

- Leveraging health and wellness centers for TB services through capacity strengthening and handholding support to deliver TB care.

- Developing Partnership and Innovation Units for technical assistance to the states for improving TB service contract management.

- Demonstrating private sector lab engagement for TB to ensure completion of the diagnostic care cascade.

Community TB care delivery

The burden of undetected TB is large in many settings, especially in high-risk groups identified under the country's National Strategic Plan (2017-25). Mapping of high-risk groups and carefully planned systematic screening for active disease among them has improved early case detection that may help to reduce the risks of TB transmission, poor treatment outcomes, undesirable health consequences, and adverse social and economic effects of the disease.

USAID's main strategies and approaches to increase TB case finding in communities and outside health facilities:

- Conducting active case-finding and TB screening activities outside of health facilities.

- Performing outreach to at-risk populations, including tribal populations.

- Developing health education, social norm shifting, population-based advocacy campaigns, and other efforts in social and behavior change (SBC) for TB elimination.

- Mobilizing champions to create awareness of TB and provide advocacy for services and peer education.

- Measuring of TB stigma and interventions to alleviate such stigma.

- Conducting gender-based analyses and interventions.

CURE

Drug-susceptible TB (DS-TB) treatment

The NTEP envisions reaching every individual with TB for the free provision of diagnosis and evidence-based treatment. In 2022, out of the notified individuals with TB from the public and private sectors, 96 percent were initiated on TB treatment. USAID's main strategies and approaches to increase DS-TB treatment success:

- Conducting a person-centered and context-dependent approaches to TB treatment.

- Assessing care cascades and improving the quality of TB care.

- Supporting the Central TB Division in evaluating direct benefit transfer (Nikshay Poshan Yojana).

- Increasing adherence and affecting successful treatment outcomes, including improved access to supportive services, counseling, nutritional support, linking to government social protection programs, e-health, behavior change communications, peer support, comorbidity support, and addressing catastrophic costs.

- Incorporating additional case management in addition to epidemiological surveillance functionalities such as refill monitoring, other adherence interventions, and clinical monitoring, plus development and linkage to laboratory and drug management modules.

- Implementing differentiated TB care approach to identify individuals with high risk of mortality, triage, and provide appropriate care to reduce chances of death.

Multidrug-resistant TB (MDR-TB) treatment

To bring DR-TB treatment closer to those with TB residences, DR-TB treatment services are decentralized to district DR-TB centers with newer, shorter, and longer oral treatment regimens. By the end of 2022, 792 DR-TB centers were functional, including 152 Nodal DR-TB centers and 640 district DR-TB centers offering decentralized DR-TB treatment services. USAID's main strategies and approaches to augment DR-TB care are:

- Delivering technical and managerial support to the Central TB Division (CTD) through technical teams of implementing partners and embedded expert consultants.

- Operationalizing of Centers of Excellence (CoEs) to improve DR-TB care through capacity building, mentoring, and clinical advice for NDR-TBCs.

- Supporting NTEP for the introduction of new drugs and treatment regimens.

- Supporting Pragmatic Clinical Trial of the modified BPaL regimen.

- Supporting NTEP in establishing and demonstrating a system for DR-TB Surveillance.

- Strengthening strategic public sector laboratory institutions - National and Intermediate Reference Laboratories (NRLs and IRLs).

- Formulating and demonstrating a model to engage private sector labs for TB/DR-TB diagnostic care cascade.

PREVENT

Prevention

USAID's main strategies and approaches to prevent the transmission of TB:

- Upgrading the digital information system for programmatic management of TB preventive treatment (PMTPT) in NI-KSHAY.

- Developing TB preventive therapy (TPT), including improved TB infection (TBI) detection and treatment for individuals at high risk of disease progression, like people with suppressed immune systems, household contacts, and young children.

- Scaling up TPT through tribal collaborative efforts, leveraging health and wellness centers, mobilizing TB champions, and expanding private sector engagement.

- Building evidence for strategic testing, including the new skin test of C-Tb, TPT in other identified risk groups, including contacts of DR-TB, and the use of digital platforms for TPT adherence monitoring integrated with Nikshay.

- Supporting the Government of India (GOI) in introducing newer vaccines and TB preventive tools.

INNOVATE

Research

USAID intends to support research that facilitates generating evidence for more effective and optimized use of currently available tools and the adaptation/uptake of new tools. USAID will support the following in collaboration with the CTD/NTEP and/or Indian Council of Medical Research (ICMR):

- Concluding the BEAT TB study with dissemination and publications of results.

- Using a Pragmatic Clinical Trial for Modified BPaL (mBPaL) treatment regimen.

- Assessing Truenat's invalid and indeterminate results for *Mycobacterium tuberculosis* and Rifampicin resistance testing at NTEP's sites and possible solutions to address the same.

- Studying the feasibility of using Trueprep (Truenat) extracted DNA for line probe assay testing in NTEP.

- Studying efficacy and effectiveness of AI technology-enabled solutions.

- Assessing and researching new initiatives under the NTEP.

- Estimating the burden of disease and measurement of linked epidemiological and socio-economic/political parameters.

- Assessing active TB case finding, direct benefit transfer scheme, and Pradhan Mantri TB Mukt Bharat Abhiyan.

Scale up of New Tools

- During this year, USAID-funded activities aim to scale up AI solutions to read and interpret line probe assay, cough-based screening solutions, modernized training system, TB champions mobilization and engagement, contracting of services with private/non-government sector.

- REACH, iDEFEAT TB, TRACE-TB and HS4TB programs will have activities to scale up new tools and innovations that will be supported with FY 2022 funds.

SUSTAIN

Commitment and Sustainability

- USAID's main strategies and approaches to strengthen domestic commitment and sustainability of the TB response:

- Providing initiatives, including the TB Corporate Pledge, focused on TB under Corporate Social Responsibility (CSR) for providing those with TB with quality care and socio-economic support while engaging communities to reduce stigma.

- Scaling of non-medical interventions by leveraging linkages, outreach, technology, and financial inclusion to strengthen services for TB elimination.

- Creating an enabling environment that addresses the demands of individuals with TB, including extending the TB Champions network activities to create a holistic engagement with multiple stakeholders to demand quality services and build the capacity of local communities to add TB awareness to their existing health efforts.

- Strengthening approaches for implementing TB purchasing arrangements to outsource TB services to non-governmental entities.

- Providing technical assistance to the Ministry of Health and Family (MoHFW) to support and steer the Tribal TB initiative, AI, institutional strengthening, and contract management.

- Creating systems to bolster GOI's flagship projects through its partners at national and state levels that support the four pillars of Ayushman Bharat.

Capacity and functioning systems

USAID's main strategies and approaches to improve procurement and supply management (PSM):

- Improving quantification, forecasting, procurement, distribution, and regulatory systems for TB medicines and supplies.

- Supporting the NTEP in improving the efficiency of TB diagnostics and drug supply chain management by systematically reviewing the current state of affairs, analyzing the root causes, and developing a realistic evidence-based plan for improved supply chain management efficiency of TB diagnostics and drugs.

- Facilitating the provision of free anti-TB drugs to individuals with TB who seek care from private healthcare providers.

- Supporting training drug store managers on inventory and supply chain management.

Monitoring and evaluation (M&E) and Health Management Information Systems (HMIS) [and implementation of the Performance-Based Monitoring and Evaluation Framework (PBMEF)]
USAID's main strategies and approaches:

- Facilitating data analytics and AI/ Machine Learning solutions under NTEP.

- Demonstrating care cascade monitoring framework using the NIKSHAY portal.

- Training on the course on program monitoring using advanced tools and techniques.

- Strengthening performance-based monitoring and evaluation framework (PBMEF).

- Strengthen the collection, management, and use of high-quality data at all levels for programmatic decision-making—e.g., target setting, planning, etc.

- Strengthening and conducting design of evaluations, assessments, and analysis to enable USAID to make informed decisions and utilize learning.

- Building a culture of learning in USAID health programming through enhanced platforms encouraging exchange and learning.

- Conducting epidemiological assessments, including TB mortality estimates, and Operational research, including the use of prescription audits and drug sales data, to improve policies and program performance, strengthen the State Training and Demonstration Center's (STDC) capacity for monitoring and evaluation, and build capacity to improve analytics, desk review, and feedback mechanism.

Human Resources for Health (HRH)
- USAID's main strategies and approaches to strengthen structural human resource policies and systems:

- Strengthening capacity and imparting skills to community health officers servicing Health and Wellness Centers (HWC).

- Developing e-training modules on TB technical, managerial components, and

- Enhancing the training capacity of the STDCs.

- Task shifting to make the best possible use of available staff.

- Developing comprehensive approaches to pre-service and in-service clinical training.

- Improve training plans, HRH assessments, and development of national cadres for community TB and health.

- Strategic planning on staffing TB's "public health function" distinct from the curative workforce.