

National Action Plan For Combating MDR-TB



USAID
FROM THE AMERICAN PEOPLE



National Institute of
Allergy and
Infectious Diseases



MDR-TB NAP Vision and Goals

Vision: *The United States will work **domestically** and **internationally** to contribute to the **prevention, detection, and control** of multidrug-resistant tuberculosis in an effort to avert tuberculosis-associated morbidity and mortality and support a shared global vision of a world free of tuberculosis.*

Goals:

1. Strengthen domestic capacity to combat MDR-TB
2. Improve international capacity and collaboration to combat MDR-TB
3. **Accelerate basic and applied research and development to combat MDR-TB**

MDR-TB NAP – Considerations

- Timely – Impact within 3-5 years
- Strengthens **existing efforts**, collaborations and programs
- **Leverages** existing infrastructure
- Emphasis on **patient impact** while balancing need for **innovation**
- Integrated with Agency Specific, overall domestic and international Strategic Goals



MDR-TB NAP Targets

By 2016

- Initiate appropriate treatment in 25% of patients with MDR-TB in 10 countries with the highest burdens of MDR-TB.

By 2018

- Initiate appropriate treatment in 35% of patients with MDR-TB in 10 countries with the highest burdens of MDR-TB.

By 2020

- Reduce by 15% the number of cases of MDR-TB in the United States.
- Initiate appropriate treatment in 50% of patients with MDR-TB in 10 countries with the highest burdens of MDR-TB.
- Reduce global TB incidence by 25% compared to 2015 levels.
- Successfully treat at least 16 million TB patients in high-burden countries.
- Achieve and maintain treatment success rates of 90% for individuals in high-burden countries with drug-susceptible TB.

**GOAL 3: Accelerate Basic and Applied
Research and Development to Combat
Multidrug-Resistant Tuberculosis**

WHO Post-2015 Strategy for TB Control

Strategy has 3 Pillars:

- Integrated, patient-centered care and prevention
- Bold policies and supportive systems
- **Intensified research and innovation**



USG Global TB Strategy: 2015 - 2019

IMPACT

A World Free of TB

Long term outcomes

Reduce TB incidence rate by 90% by 2035
Reduce TB mortality rate by 95% by 2035

Medium term outcomes

During 2015-2019:
Reduce TB incidence rate by 25%
Maintain treatment success rate 90%
Successfully treat 13 million patients
Initiate treatment for 360,000 DR-TB patients
Provide ART for 100% of TB/HIV patients

Objectives

Improve access to high quality, TB, DR TB, & TB/HIV services

Prevent transmission and disease progression

Strengthen TB service delivery platforms

Accelerate research and innovation



Bench to Bedside: USG Contributions to TB Research

Basic and
Translational
Research

Clinical Trials

Field
Demonstrations

Implementation
and Policy
(domestic and
international)

U.S. Federal TB Task Force



**Only major agencies/programs listed below*



National Institutes
of Health



CENTERS FOR DISEASE
CONTROL AND PREVENTION



USAID

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PEPFAR

U.S. President's Emergency Plan for AIDS Relief



AHRQ

Advancing
Excellence in
Health Care

On-going USG TB Research Efforts

- All aspects of **basic, translational and clinical** research
 - Product development (**drugs, vaccines, diagnostics**)
 - Clinical trials to evaluate new drugs, vaccines, diagnostics
 - Extensive clinical research/trials infrastructure
(**adult, pediatrics, HIV/TB**)
- **Epidemiological** research in the US and globally
- **Operational and implementation** research to support development of new diagnostic, treatment and prevention paradigms
- Clinical and operational research to inform **domestic and global TB control policy**
- **Training** in clinical and biomedical research



Goal 3 – Areas of Emphasis

- 1) Increase options for **preventing** *Mtb* infection, transmission, and TB disease
- 2) Improve the **diagnosis** of TB (latent infection, active drug-sensitive and M/XDR-TB)
- 3) Improve **treatment options** for individuals with drug-sensitive and M/XDR-TB
- 4) Increase the **capacity** of TB endemic countries to conduct biomedical and clinical research in TB



1) Increase options for preventing *Mtb* infection, transmission, and TB disease

- Novel vaccines and other preventive strategies
- Methodologies to prevent transmission and/or development of TB and M/XDR-TB

Proposed Activities:

- Increase **knowledge and collaborations** among stakeholders
- Contribute to more **rational design** of vaccines
- Support transition of candidates into **clinical trials**
- Explore vaccine & chemo-prophylactic approaches to **prevent TB, M/XDR-TB** (high risk persons)
- Evaluate **impact & cost-effectiveness**: TB preventive measures in high burden countries

2) Improve the diagnosis of TB (latent infection, active drug-sensitive and M/XDR-TB)

- New tools/approaches to detect & initiate treatment of M/XDR-TB
- Biomarkers to detect latent & active TB; likelihood of progression to active disease

Proposed Activities:

- Understand **genetic diversity** of M/XDR *Mtb* strains to contribute to new diagnostic tests
- Enhanced research to identify and validate **novel biological markers and signatures** to detect likelihood of progression to active TB
- Support evaluation of promising **new diagnostics** (adults and children)
- Develop **evidence-based approaches** to optimize use of diagnostics and algorithms, and evaluate their impact

3) Improve treatment options for individuals with drug-sensitive and M/XDR-TB

- Improve use of **existing** TB drugs
- Enhance knowledge to enable optimal and safe use of **newly registered** TB drugs
- Support development of **novel** drugs and shorter, less toxic, more effective M/XDR-TB treatment regimens & methodologies

Proposed Activities:

- Develop & pilot strategies to **improve current treatment outcomes**
- Support clinical trials of **shorter regimens using existing & newly registered drugs**
- Contribute to knowledge of **Delamanid & Bedaquiline** to inform M/XDR-TB treatment guidelines
- Support discovery, development and testing of **new drugs and strategies** to shorten treatment and improve patient safety

4) Increase the capacity of TB endemic countries to conduct biomedical and clinical research in TB

- Expand existing clinical trial sites and establish new clinical sites
- Identify markers of treatment response and/or protection to expedite clinical trials

Proposed Activities:

- Support capacity in TB endemic countries for **clinical trials & biomedical research**
- Expand capacity for biomarker discovery and **validation**
- Establish **research training** centers
- **Increase collaborations** with TB endemic countries and their TB patients

Reporting

“No later than **September 30, 2016** and each year thereafter until 2020, the Secretaries of State and HHS, the Administrator of USAID, and heads of other relevant Departments will **submit a joint report on progress in implementation of the National Action Plan**. Each year, the reports will be made available to the public and be submitted to the Assistant to the President for Science and Technology and Director of OSTP, the Assistant to the President for Homeland Security and Counterterrorism, and the Director of the Office for Management and Budget **to inform program planning and the annual budget cycle.**”

Objective: 3.1: Increase options for preventing active TB, latent TB infection, and TB transmission

Sub-Objective: 3.1.1. Advance research and development of novel vaccines

- **Milestone (year 1):** NIH will expand its dialog among basic scientists, funders, and vaccine developers to identify novel strategies for vaccine development, encourage research related to vaccine design, and educate partners about resources available to contribute to vaccine development.
 - [RELEVANT ACTIVITIES/ACCOMPLISHMENTS]

- **Milestone (year 1):** NIH will continue to support studies to map the diversity of immune responses required for vaccine efficacy.
 - RELEVANT ACTIVITIES/ACCOMPLISHMENTS]

- **Milestone (year 3-5):** NIH will continue to support research, pre-clinical studies, and clinical trials and studies for the evaluation of new vaccines, adjuvants, and preventive drugs.
 - RELEVANT ACTIVITIES/ACCOMPLISHMENTS]

- **Milestone (year 3-5):** NIH and CDC will intensify collaborations with domestic and international vaccine developers to leverage pre-clinical and clinical resources for vaccine development.
 - RELEVANT ACTIVITIES/ACCOMPLISHMENTS]

- **Milestone (year 3-5):** USAID will support platforms for TB vaccine researchers and key stakeholders in countries to facilitate collaboration and increase knowledge on TB vaccine research.
 - RELEVANT ACTIVITIES/ACCOMPLISHMENTS]

- **Milestone (year 3-5):** State and DOD will explore a proof-of-concept randomized controlled study to assess whether BCG can provide short term protection to adults for prevention of TB infection during extended travel to high-risk countries (for example, U.S. active military personnel and U.S. diplomatic corps); the published risk of infection is 4–8 percent for such travelers.
 - RELEVANT ACTIVITIES/ACCOMPLISHMENTS]

Action Items for NIH I/C

- NIAID will coordinate (for now) reporting of NIH relevant NAP activities
- USAID will produce consolidated report for Goals 1-3
- Expect to have Y1 contributions filled out by end of July 2016

Please respond by April 11:

- Identify who at your I/C will be the point of contact for annual reporting – send names to csizemore@niaid.nih.gov
 - Will send dates for first report
 - Will distribute template for reporting (WORD document or Excel)
 - Will review final report for clearance
- How frequently do we meet to discuss Goal 3 activities - suggest?
- Let us know who from your I/C will attend a “Goal 3 meeting” with all relevant USG agencies (need names to set date)?