Accelerating Development of **Essential New Tools to End TB**

The UN Sustainable Development Goals aim to end the tuberculosis (TB) epidemic by 2030. To address growing drug resistance and meet this global target, more effective drugs, diagnostics and vaccines are urgently needed. The United Nations High-Level Meeting on TB in 2018 created a critical opportunity to strengthen the global response to TB by taking clear and decisive action to support the development of new tools for TB.

Why we need new tools

TB is the world's deadliest infectious disease and it is evolving.

About **10 million** people became sick with TB and about **1.5 million** people lost their lives to TB in 2018 alone.

If not addressed, drug-resistant TB could cause **75 million deaths** and cost the global economy as much as **US$16.7 trillion by 2050**.

Existing tools are not sufficient to meet global targets to end TB. **New vaccines, drugs, and diagnostics will be required to end TB by 2030.**

The following commitments must be prioritized by Heads of State and governments to accelerate research and development of the new tools that are urgently needed to end TB.

Accelerate development of essential new tools to end TB

- Create research-enabling environment that streamlines and expedites innovation and promotes collaboration across UN member states in order to introduce new tools to prevent, diagnose and treat TB in all its forms, including:
  - A two-month or less oral cure for TB and its drug-resistant forms before 2028
  - One or more new or repurposed vaccines ready to enter the registration process for global use by 2025
  - Affordable point-of-care TB diagnostics that can identify TB disease and drug-resistance, as well as tests to detect TB infections
- Acknowledge that TB innovation is a shared responsibility and ensure that all R&D efforts are needs-driven, evidence-based and guided by principles of affordability, efficiency, equity and collaboration. Importantly, as a central component of the response to antimicrobial resistance (AMR), TB will require models of innovation that delink the costs of R&D from prices and volumes of sales to facilitate equitable and affordable access.

Invest the funds necessary to end TB

- Increase funding for TB research to close the US$1.3 billion annual funding gap, for example, through each member state spending up to or beyond 0.1% of its Gross Domestic Expenditure on Research and Development (GERD) on TB research; and implement long-term funding strategies to ensure the sustainability of research progress and pipelines.

New Vaccines

- **Vaccines are the most successful and effective public health interventions to reduce** and even eradicate life threatening infectious diseases, but the only licensed vaccine to prevent TB, BCG, is unreliable in preventing TB in adolescent and adult populations – those most at risk for getting sick with TB and transmitting it to others.
- An effective and affordable **TB vaccine** suitable for use in all at-risk populations and capable of breaking the cycle of transmission is essential for ending this epidemic.
- A new effective **TB vaccine will** reduce the need for antibiotics and **help curb the rise of AMR**.

New Diagnostics

Access to accurate and rapid diagnosis is often limited in places that bear the highest burden of TB, leading to delayed treatment and further spread of the disease. We need:

- An **easy-to-use, low-cost, non-sputum-based rapid test** for diagnosing active TB that can be deployed in active case finding strategies or used in primary healthcare facilities.
- **Rapid drug resistance tests** that can determine response to critical drugs to direct patients to appropriate treatments and safeguard medicines against AMR.
- An **incipient TB test** to identify individuals at high risk of progression from latent TB infection to active disease and enable targeted preventive treatment.

New Drugs

- TB treatments take **too long to cure**, are **too complicated** to administer, and can be **toxic**.
- Treating drug-resistant TB is especially challenging, with low success rates even after years of treatment including thousands of pills per patient and a high risk of serious side effects.
- To have a transformative impact, we need:
  - **Short, simple and affordable** TB regimens that work in all people with TB.
  - A sustainable **pipeline of combination treatments** with broad utility.

We have made progress in developing new tools

- Approximately twenty years ago, there was only one vaccine candidate in early clinical development. Today, there are 15 candidates in the global TB vaccine clinical pipeline, with several more in preclinical development. Results from recent clinical trials demonstrate unprecedented progress and offer a unique opportunity for the field to learn, grow and increase momentum – and offer a real chance to have new vaccines developed by 2025.
- The Xpert MTB/RIF test can detect TB and rifampicin resistance in decentralized settings and has reduced the time to recieve test results from months to hours. Biomarkers have been identified that make a point-of-care triage test possible, and drug resistance testing could be transformed with sequencing tools. The urine based TB LAM test brings care closer to patients and has the potential to help find the missing millions of TB cases.
- In the past five years, three new drugs received accelerated regulatory approval, including one that was approved as part of a regimen for some of the most highly drug-resistant forms of TB. These are the first new TB drugs in 40 years and they reflect a growing clinical pipeline for drugs which now boasts over a dozen new and repurposed compounds.

Success will require increased and sustained investment in R&D

- The Global Plan to End TB calls for $10.8 billion for TB R&D between 2018-2022; however, TB research currently receives one-third of this target annually—and the majority is provided by just five funders.
- Long-term funding strategies are needed to ensure the sustainability of research progress and pipelines, and innovative mechanisms are needed to incentivize private sector engagement in TB R&D.

FIND Because diagnosis matters

TBVI TuBerculosis Vaccine Initiative

TB Alliance

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