New TB Tools: 
*Is ending TB (finally) within sight?*

We need bold Member State action to develop and roll out the new tuberculosis (TB) tools we need to end the TB pandemic by 2030. The 2023 United Nations High-Level Meeting (HLM) on TB is a critical opportunity to urgently advance the development and delivery of new TB diagnostics, treatments, and vaccines that are accessible and affordable to all who need them. The Political Declaration on TB is also the first political declaration on health that explicitly recognizes the human right to enjoy the benefits of scientific progress – Member States must now commit the necessary resources to make this goal a reality.

**Why we need new TB Tools**

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

COVID-19-related setbacks have reversed a decade of progress on TB.

About 10.6 million people became sick from TB and 1.6 million people lost their lives to TB in 2021 alone.

Drug resistant TB (DR-TB) is a key driver of antimicrobial resistance (AMR). Multidrug-resistant TB and extensively drug-resistant TB are both on the rise. Less than a third of the half a million people estimated to have fallen sick with DR-TB in 2021 accessed treatment.

Without further action, a projected 31.8 million TB deaths and US$17.5 trillion in economic losses will occur by 2050.

**Heads of State and Governments must prioritize the following commitments to accelerate the development and delivery of the new tools that we urgently need to end TB.**

**Accelerate development of essential new tools**

Create a research-enabling environment that streamlines and expedites innovation and promotes collaboration across UN Member States in order to develop and introduce new tools to prevent, diagnose, and treat all forms of TB and for people of all ages, and to ensure equitable access to the benefits and applications of TB research, including:

- **Shorter and more acceptable treatment regimens** with less side effects for TB, DR-TB and TB preventative therapy (TPT), applicable to all, including adults, children, adolescents and those who are pregnant or lactating.
- **Affordable, point-of-care TB diagnostics** and new rapid molecular tests and user-friendly next generation sequencing to identify drug resistance and select the most appropriate treatment regimen.
- **One or more new or repurposed vaccines** that are suitable for use in all populations, ready to enter the registration process for global use within five years, and systems in place to provide access to all in need.

Member States must also acknowledge that TB innovation is a shared responsibility and ensure that all research and development (R&D) efforts are needs-driven, evidence-based, and guided by principles of affordability, efficiency, equity, and collaboration.

**Invest the funds necessary to end TB**

- Increase funding for TB research to meet the US$5 billion annual funding target outlined in the Global Plan to End TB 2023-2030, including $2 billion for drugs, $1.25 billion for vaccines, and $1 billion for diagnostics.
- **All Member States contribute their fair share** by spending at least 0.15% of their Gross Domestic Expenditure on R&D (GERD) on TB research; and implement long-term funding strategies to ensure the sustainability of research progress and pipelines.
- **Attach access conditionalities to TB R&D across the R&D continuum**, including to all publicly funded research, to ensure that rewards for innovation are independent from rights to market exclusivity.
New drugs

Treatment for TB is long, complicated, often toxic, and expensive; drug resistance to available antibiotics is growing.

- Treating drug-resistant TB is especially challenging, with low success rates even after years of treatment including a high risk of serious side effects.
- New, shorter, simpler, safer, and more effective therapeutic drug regimens are urgently needed to eliminate TB. Researchers are seeking to develop a sustainable pipeline of novel drug regimens that can effectively treat every person with TB.
- Member States and other duty bearers must take action to implement the shortest available regimens – one month or once-weekly for TB prevention, four months for drug-sensitive TB, and six months for drug-resistant TB — by the end of 2024.

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.

- Easy-to-use, low-cost, non-sputum-based, rapid tests to diagnose active TB that are suitable for use in primary healthcare and community settings and that work through the collection of easily accessible samples (e.g. urine, stool).
- Rapid drug resistance tests that can determine response to critical drugs, inform the treatment selection, and safeguard medicines against AMR.
- A simpler test to proactively screen individuals at high risk of progression from TB infection to active disease and enable targeted preventive treatment.
- Digital and AI-based diagnostic and decision-making tools to support community-wide screening and early detection of all forms of TB.

New vaccines

New TB vaccines are essential to end TB, but the only licensed TB vaccine, BCG, is ineffective in adolescents and adults who are most at risk of developing and spreading TB.

- New TB vaccines would break the cycle of TB morbidity and mortality, fight global AMR, advance health equity, avert millions in household catastrophic costs, and improve global macro-economic growth for years ahead.
- A vaccine that is 50% effective in preventing disease among adolescents and adults could avert up to 76 million cases and 8.5 million deaths over 25 years.
- New TB vaccines could be ready for licensure and roll-out within five years. Multiple vaccines are in efficacy trials and work is underway to develop next-generation vaccines based on mRNA and other promising platforms.

Progress in developing new tools is accelerating

In the past ten 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.

Major developments in diagnostic testing are supporting a global shift towards decentralized, point-of-care testing. New cartridge-based tests cut the time it takes to diagnose TB and DR-TB from months to hours, while next generation sequencing holds additional potential for full resistance profiling in a single diagnostic test. Alternative sampling methods (e.g. urine and stool) also create new opportunities to screen key populations and help find the “missing millions” of TB cases.

Twenty years ago, there was only one vaccine candidate in the clinical trial pipeline. Today, there are at least 15 candidates, 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.

Success requires increased and sustained investment

TB research currently receives only one-fifth of the the US$5 billion annual funding target each year, passing US1 billion in annual funding for the first time in 2021—the majority is provided by just five funders.

Long-term funding strategies are needed to ensure the sustainability of research progress and pipelines and deliver new TB tools to those who need them, and innovative mechanisms are needed to incentivize private sector engagement in TB R&D.

References

WHO Global Tuberculosis Report 2022
Stop TB Partnership. The Global Plan to End TB 2023-2030.