

New diagnostic tools needed to end TB, world's leading infectious disease killer

With over 1.5 million deaths and 3.6 million people undiagnosed but contagious, new tests are needed to stop suffering and ongoing transmission

Today's response to the global tuberculosis (TB) epidemic demands **urgent and effective action**.

This curable disease, known to humanity for thousands of years, is now the top infectious disease killer on the planet, with 9.6 million new infections identified per year and 4100 deaths every single day. TB and HIV/AIDS are “partners in crime”, often co-infecting the same people, and reducing their hope for life, especially when they have forms of TB that are resistant to treatment by available drugs. The very limited investments in TB research and development (R&D) have left the TB community to fight the disease with old and inadequate tools. In its *End TB Strategy*, the World Health Organization (WHO) has set global targets to eliminate TB as a global health threat...but at the current rate of decline of TB incidence, the world will only achieve the End TB targets by the year 2182.



Although TB is treatable, undiagnosed TB can lead to significant complications and death.

The Stop TB Partnership-endorsed *Global Plan to End TB* calls for **highly sensitive diagnostic tests** for all forms of TB that can be implemented at the point of care. Without investment in research and development for new diagnostics, treatments and vaccines, the goals of the *End TB Strategy* will not be realized.

Failure to invest immediately in the tools needed to achieve the End TB milestones will result in **substantial human and financial costs**. It is estimated that a five-year delay in investing in R&D could result in an additional 8 million TB cases and 1.4 million TB deaths by 2030. These additional cases are estimated to lead to costs of US\$ 5.3 billion over five years for treatment alone. When productivity losses from preventable TB illness and deaths are included, these costs climb to US\$ 185 billion over five years.

The case for new diagnostics



3.6 million TB cases are left undiagnosed each year.

Every year, one in three people who fall ill with TB are left undiagnosed or not registered by health systems. **These “missing” 3.6 million people** are at the root of why TB transmission continues at such high levels. The scale-up and more efficient implementation of existing diagnostic tools will help countries find and treat these millions of people. However, reaching the *End TB Strategy* targets (see below) will require a drastic scale-up in case detection – a task that can only be driven by major advances in new diagnostic test technologies.

TB is readily curable with appropriate treatment, but the **inappropriate use of TB drugs**—in large part due to prescriptions based on presumptive diagnosis rather than confirmed testing for TB and drug susceptibility—has led to an increase in drug-resistant strains of the disease.

New diagnostic tools and testing strategies are required in three areas: 1) a range of tests for TB case detection that can be deployed at all levels of the health care system, including in front line health care settings; 2) rapid and simple tests for the detection of drug-resistance in decentralized settings; and 3) tests for predicting the risk of progression from latent infection to active TB disease.

The Global Plan to End TB estimates that developing effective diagnostic tools for tuberculosis requires an investment of at least US\$ 1 billion over the next five years.

End TB Strategy targets (WHO)

WHO's *End TB Strategy*, building on the U.N.'s Sustainable Development Goals, has the following targets (relative to 2015 levels):

- **90% reduction in TB incidence** rate by 2035
- **95% reduction in TB deaths** by 2035
- **Zero** TB-affected families facing catastrophic costs due to TB

A portfolio of solutions

FIND is working to improve TB diagnosis using many approaches. Here are three examples:

- ♦ **Ready for deployment:** FIND is working to roll out Omni, a new portable testing platform. It is small and battery-operated, making it possible to run TB tests in settings where most patients present for diagnosis. This tool will make TB diagnosis faster, as well as making it easier to detect drug-resistance at the time of diagnosis. This in turn will make treatment more effective, and help reduce the transmission of drug-resistant strains of TB. *(Funding required: US\$ 12 million over five years)*
- ♦ **Near-term (3 years):** A stool test to detect TB in children and adults. FIND is supporting the development of a test that would use stool samples instead of sputum, greatly simplifying the diagnosis of TB in children and people living with HIV. *(Funding required: US\$ 2.5 million over three years)*
- ♦ **Long-term (5 years):** Next Generation Sequencing (NGS) technology can quickly identify up to 200 mutations in the TB bacterium, allowing the rapid identification of antibiotic-resistant strains. This tool placed in reference laboratories in affected countries would give the global health community a more accurate picture of which drug-resistant strains exist and where they are found. TB treatments could then be targeted appropriately. Furthermore, such a solution could eventually be used for other diseases as well. *(Funding required: US\$ 8 million over five years.)*



GeneXpert® Omni, an example of a next-generation molecular diagnostics system which, when used in front-line health care settings, will lead to fast and accurate treatment, helping to find the missing 3.6 million people living with undiagnosed or untreated TB.

A snapshot of FIND's accomplishments in TB

- ♦ The current Xpert MTB/RIF test enables the detection of TB infection and first-line drug resistance in **90 minutes** at a hospital, rather than up to 120 days to detect drug resistance at higher-level laboratory using other, older methods.
- ♦ Six new diagnostic technologies have improved the detection and treatment of TB and MDR-TB, **saving an estimated 300,000 lives** per year.
- ♦ Through its TB programme, FIND has built local diagnostic capacity by training 4,400 health care workers in over 360 laboratories and testing sites in 39 countries.
- ♦ FIND specimen banks help identify promising new tests early and reduce the costs of developing new diagnostic tests. The TB collection includes 60,000 samples in the form of sputum, serum, EDTA plasma, P800 plasma and urine, as well as resistant strains.

About FIND

Founded in 2003, FIND is an international non-profit organization that enables the development and delivery of essential diagnostic tests for diseases of poverty, including tuberculosis, malaria, HIV/AIDS, sleeping sickness, leishmaniasis, Chagas disease, Buruli ulcer and hepatitis C. FIND works through partnerships to overcome barriers to innovation and use of diagnostic solutions in low-resource settings. Over the last 12 years, FIND's programmes have supported the delivery of 11 new diagnostic tools, including six for TB, and helped transform the diagnostics landscape for TB and other diseases. FIND supports diagnostics development through specimen banks, reagent development, and better market visibility, and supports the deployment of diagnostics through quality assurance and lab strengthening. Learn more about FIND and our programmes at www.finddx.org.