Stop TB Partnership

New Diagnostics Working Group

It's
TIME
to diagnose TB

TB #DIAGNOSISMATTERS

TB kills more people than any other single infectious disease, including HIV.

In 2018, **10 million people fell ill with TB**, of which ~**1 million were children**.

Of those 10 million, an estimated **3 million went undiagnosed** and **1.5 million died** from the disease.

~**1.7 billion people worldwide have a latent TB infection** (LTBI) and are at risk of developing an acute form of TB over their lifetime.

Diagnostics are needed to detect exposure, diagnose disease and drug resistance, monitor improvement under treatment in both primary healthcare and laboratory settings, as well as strengthen surveillance systems.

An estimated **54 million lives were saved through TB diagnosis and treatment** between 2000 and 2017, but there are still large and persistent gaps in detection and treatment.

THE DIAGNOSTICS CHALLENGE

- **Symptoms:** Symptoms of active lung TB are common, such as cough with sputum and blood, chest pains, weakness, weight loss and fever
- **Poor sensitivity:** Historical diagnostics methods using microscopy detect only half of TB cases and cannot detect drug-resistance
- **Vulnerable populations:** TB in children and HIV positive people is especially hard to diagnose
- **Time to results:** Microscopy can take weeks, if not months, putting patients' lives at risks
- **Cascade of care:** TB patients with drug-resistant strains often go undiagnosed and untreated
- **Access:** Availability of rapid molecular tests such as Xpert MTB/RIF® is limited

High accuracy, short time to obtain a result, and simple use at an **affordable price** are significant challenges for current TB diagnostic tools.

CLOSING GAPS IN CARE: THE MISSING MILLIONS

An estimated **3 million infected people go undiagnosed**. Why is it important that they are found? Because they will continue to infect others and we will not be able to control the disease and ultimately end TB.

If someone has TB but is not diagnosed for a year, they can infect between 15 and 20 people. It is critical that they are found as this is one of the surest ways to cut the chain of transmission in the community.

DRUG-RESISTANT TB, A GROWING THREAT

Urgent action is required to improve the coverage and quality of diagnosis, treatment and care for people with drug-resistant TB. While treatable and curable with second-line drugs, successful patient outcomes at present are low while regimens are costly and incur side effects.

Rapid drug-resistance tests are needed to enable treatment regimens tailored to individuals and to help safeguard medicines against antimicrobial resistance (AMR).

3 MILLION GLOBAL GAP

7 MILLION DETECTED AND NOTIFIED

3 MILLION PEOPLE WITH TB UNDIAGNOSED OR UNREPORTED

TACKLING THE DRUG-RESISTANT TB (DR-TB) PUBLIC HEALTH CRISIS

ONLY **ONE IN THREE** PEOPLE **ILL WITH DR-TB** ARE PUT ON TREATMENT

ESSENTIAL MEDICINES AND ESSENTIAL DIAGNOSTICS: A PACKAGE DEAL

The World Health Organization (WHO) has published a Model List of Essential In Vitro Diagnostics. **The list includes 10 diagnostic tests for TB.**

This landmark development signals the vital importance of linking use of medicines with diagnostic tests to advance the Universal Health Coverage (UHC) agenda.

PRIORITIES FOR POLICYMAKERS

• Adopt a national essential diagnostics list
• Provide in-country access to diagnostics, including rapid molecular diagnostics
• Set-up robust surveillance mechanisms
• Identify your missing millions/thousands
• Strengthen healthcare patients pathways
• Provide in-country access to DR-TB treatments

UN **HLM** → END TB
26 September 2018

World leaders who participated in the 2018 United Nations General Assembly High-level meeting on TB adopted a number of commitments to pave the way to eliminating TB.

• Provide diagnosis and treatment – with the aim of **successfully treating 40 million people** with tuberculosis by 2022.

• Provide diagnosis and treatment - with the aim of **successfully treating 3.5 million children** with TB by 2022.

• Provide diagnosis and treatment – with the aim of **successfully treating 1.5 million people with drug-resistant TB**, including 115 000 children with drug-resistant TB, by 2022.

BENEFITS OF BETTER, MORE WIDESPREAD TB DIAGNOSTICS TOOLS

• Earlier detection and appropriate treatment for patients
• Limits risk of infection spread
• Improved disease surveillance capabilities
• Lower risk of development of AMR
• Lower burden on healthcare systems and communities

THE LANDSCAPE FOR TB DIAGNOSTICS IS RAPIDLY EVOLVING

Easy-to-use, robust, reliable and highly accurate tests which can be used in routine clinical settings, particularly at the lower levels of care are the need of the hour.

Organizations active in the field of global health, such as the Foundation for Innovative New Diagnostics (FIND), are working with key stakeholders and industry to identify specific needs and translate them into target product profiles. These result in **a technology pipeline of promising new products**, several of which are currently undergoing evaluation in field studies.

Specifically, the diagnostics technology landscape has witnessed progress with the development of tools for screening and triage, sample transport, automated microscopy, culture-based tools for diagnosis of TB and drug susceptibility testing, molecular tests to detect DR-TB exposure and TB disease, including sequencing methods, as well as R&D on biomarkers.

These advances go hand in hand with efforts to ensure that diagnostics are accessible and affordable to those in need.

THE STOP TB PARTNERSHIP'S NEW DIAGNOSTICS WORKING GROUP

The Stop TB Partnership's New Diagnostics Working Group (NDWG) is working to foster the development and evaluation of new diagnostics for TB.

It brings together experts representing stakeholders from academia, NGOs, multilaterals and governmental institutions, TB high-burden countries, industry, and the patient community. The three current NDWG task forces focus on:

• Biomarkers or biosignatures for TB point-of-care tests
• Next-generation drug susceptibility testing in alignment with new treatment guidelines and future drug regimens
• Fostering the development and evaluation of tests for progression of LTBI to active disease

http://www.stoptb.org/wg/new_diagnostics/

References:

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END TB