Stop TB Partnership hosted by UNOPS

UN HLM END TB 26 September 2018

MEDIA BRIEF

TB INNOVATION AND THE UN HIGH-LEVEL MEETING (UN HLM) ON TB

Context

Tuberculosis (TB) is the leading cause of death among infections and the ninth overall leading cause of death worldwide, ranking even above HIV/AIDS.[1] In 2017, an estimated 1.7 million people were dying of TB, 10 million people developing TB, and nearly 600 000 new incidences of multidrug-resistant TB (MDR-TB) globally.

Despite progress made in the last two decades, the incidence of TB is not declining fast enough to end the disease as envisaged under the Sustainable Development Goals[2]. TB is curable and preventable. All people developing TB, including drug-resistant TB, need to be diagnosed and treated, and those at highest risk of developing TB (contacts of patients, people living with HIV, etc.) need to receive preventive therapy. Currently, only about 60% of TB and about 25% of drug-resistant TB are notified as receiving treatment; the remaining are the millions of people who are "missing" from care. Coverage levels are lower for children and preventive therapy coverage is minimal.

There are a number of challenges that need to be addressed in order to end TB. One of them is the adoption and scale-up of innovations.

The Challenge: Sub-Optimal Roll-Out and Adoption of New TB Innovations

The uptake of new innovations for preventing, diagnosing, and treating TB remains inadequate for achieving the Stop TB Partnership's ***Global Plan*** to End TB 2016-2020[3] and the WHO's End TB Strategy, the latter which includes 2030 targets to reduce the TB incidence rate by 90% and TB deaths by 80%, using 2015 as a baseline.

The availability of new TB products and technologies in a country does not necessarily correlate to adoption, correct usage, scale-up, or significant public health impact. To date, experience with new TB diagnostics, in particular, suggests that many national TB programs (NTPs) in high burden countries are unable to adopt and scale-up new tools, even when they are backed by evidence and global policy recommendations, due to issues such as lack of ambition, insufficient funding, training, and weaknesses in health system planning and management.[4] [5]

A key example demonstrating the above is the Xpert MTB/RIF assay—a cartridge-based fully automated nucleic acid amplification test (NAAT) for TB case detection and rifampicin resistance testing—which entered the market

in 2010 and as of 2016 had over 16 million tests performed in 122 countries.[6] However, the old technology of sputum microscopy is still the mainstay of diagnosis for most high TB burden countries. The roll-out of Xpert has highlighted the following gaps which have constrained the tool's scale-up and limited its impact on patient outcomes: (i) High cost of Xpert for under-funded NTPs, (ii) Unavailability of a complete solution package, particularly comprehensive training, quality assurance, implementation plans, and

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[1] WHO, "Global Tuberculosis Report 2017," ***http://apps.who.int/iris/bitstream/10665/259366/1/9789241565516-eng.pdf?ua=1***, 2017, page 1

[2] Health targets for SDG 3. **http://www.who.int/sdg/targets/en/**

[3] Stop TB Partnership. Global Plan to End TB 2016-2020 ***http://www.stoptb.org/assets/documents/global/plan/GlobalPlanToEndTB_TheParadigmShift_2016-2020_StopTBPartnership.pdf***

[4] M. Pai and K.M. Palamountain, "New tuberculosis technologies: challenges for retooling and scale-up," The International Journal of Tuberculosis and Lung Disease, 16(10):1281-1290, 2012

[5] Stop TB Partnership and MSF. Out-of-step 2017: TB Policies in 29 Countries. ***http://www.stoptb.org/assets/documents/outofstep/UNOPS_out_of_step_2017_55_online.pdf***

[6] Heidi Albert, Ruvandhi R. Nathavitharana, Chris Isaacs, Madhukar Pai, Claudia M. Denkinger, Catharina C., "Development, roll-out and impact of Xpert MTB/RIF for tuberculosis: what lessons have we learnt and how can we do better?" European Respiratory Journal 2016; DOI: 10.1183/13993003.00543-2016, 2016

service and maintenance support, and (iii) Lack of impact assessments. In addition, the insufficient focus has been given to effective linkage of diagnosis to care of diagnosed patients, and weak health systems have undermined clinical impact.

Another key example of the sub-optimal roll-out and country adoption of new TB innovations is the case of TB-LAM, a rapid, point-of-care urine test used to diagnose active TB in individuals with advanced HIV. In 2015, the WHO recommended the use of TB-LAM, but as of August 2017, only 2 to 3 countries had incorporated LAM into their policies for the diagnosis of TB in critically ill HIV patients.[7] [8] There has been a low uptake of the test globally due to lack of political will, stemming from the following reasons: (i) The misconception that target populations for TB patients are being holistically screened and diagnosed through other tests, (ii) Lack of knowledge or understanding on how to effectively introduce the test at a national level, and (iii) Lack of funding—despite the test being inexpensive (priced between 2.66 and 3.50 USD per test) and the ability of donors such as the Global Fund and PEPFAR to purchase TB-LAM tests for countries.

The Opportunity: UN High-Level Meeting (UN HLM) on TB

In response to the scale of the global TB epidemic, the critical need to accelerate the decline of TB to meet global targets, and the sub-optimal roll-out and adoption of new TB innovations, the United Nations High-Level Meeting (UN HLM) on TB on 26 September 2018 presents an unprecedented opportunity to galvanize much-needed attention, resources, and accountability to drive progress toward the global community's ambitious goal of ending TB by 2030. To bend the curve on TB, we urgently need to adopt and scale-up new, quality-assured drugs, diagnostics, and approaches to finding and treating patients, which will require being more innovative and collaborative than ever before.

In the political declaration that is expected to be signed at the HLM, states will reaffirm their commitment to end the TB epidemic globally by 2030, in line with the Sustainable Development Goals (SDGs) target, commit to end the epidemic in all countries, and pledge to provide leadership and work together to accelerate national and global collective actions, investments, and innovations urgently to fight this preventable and treatable disease. With regards to R&D and innovation, particular focus is being placed on the development and evaluation of better diagnostics, drugs, treatment regimens, and vaccines, as well as other innovative care and prevention approaches, such as to address social and economic factors of the disease.

The declaration will also commit to create an environment conducive to R&D of new tools for tuberculosis, and to enable timely and effective innovation and affordable and available access to existing and new tools and delivery strategies and promote their proper use, by fostering competition and collaboration, removing barriers to change, promoting voluntary technology transfer on mutually agreed terms, and work towards improving regulatory processes and capabilities.

The political declaration that the UNHLM will adopt has bold targets at the global level which need to be translated into country level targets, plans and budgets, with a robust accountability framework to ensure that these are met. Key global targets in the draft declaration include:

Between 2018 to 2022, 40 million people with TB will be treated, including 3.5 million children and 1.5 million people with drug-resistant TB, which will mean that there will be no one with TB missing from treatment in 2022.

At least 30 million people will receive preventive TB treatment by 2022.

Investments in TB care and prevention should reach 13 billion USD per annum – currently, about half of this is available.

In addition, investment of 2 billion USD per annum on research and development of new tools – currently there is a funding gap of 1.3 billion USD per annum.

*To learn more, please consult **www.stoptb.org** or write to **communications@stoptb.org***

[7] Stop TB Partnership and MSF:
http://www.stoptb.org/assets/documents/outofstep/UNOPS_out_of_step_2017_55_online.pdf
[8] Adam Almeida, "The LAM Test: Vital for Diagnosing TB in People with Advanced HIV," Treatment Action Group, August 2017.