THE FUNDING GAP IN TB DIAGNOSTICS R&D

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WITH THANKS TO MIKE FRICK

11 OCTOBER 2017
FIND & NDWG SYMPOSIUM
GUADALAJARA, MEXICO

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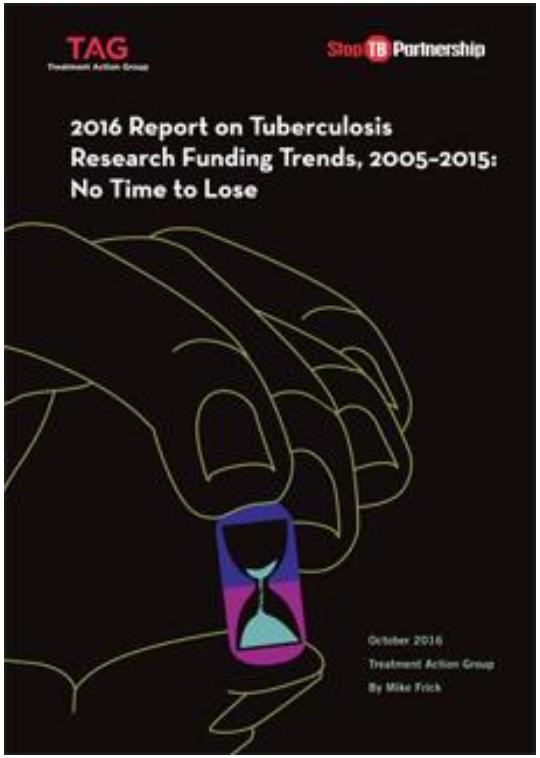
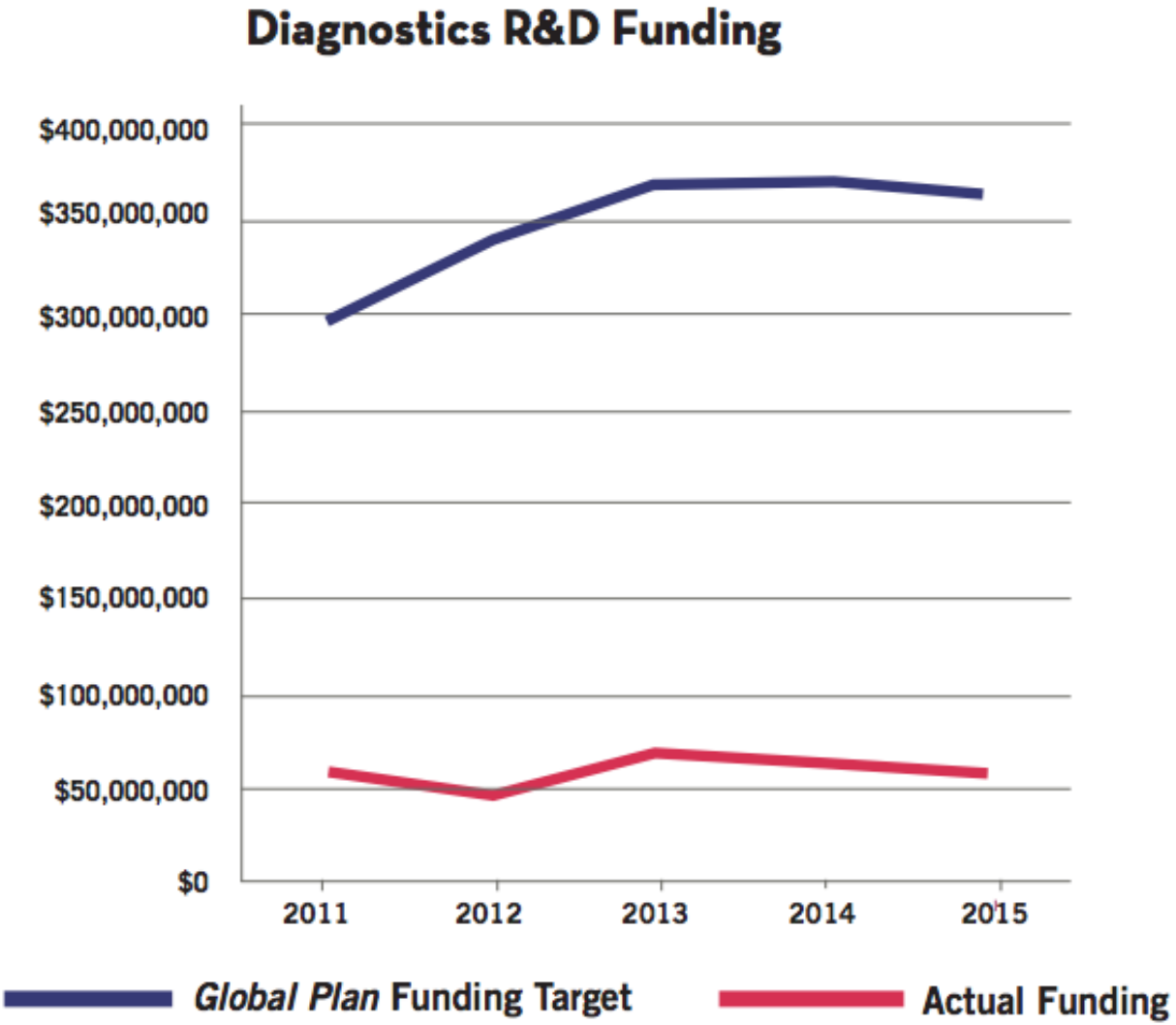
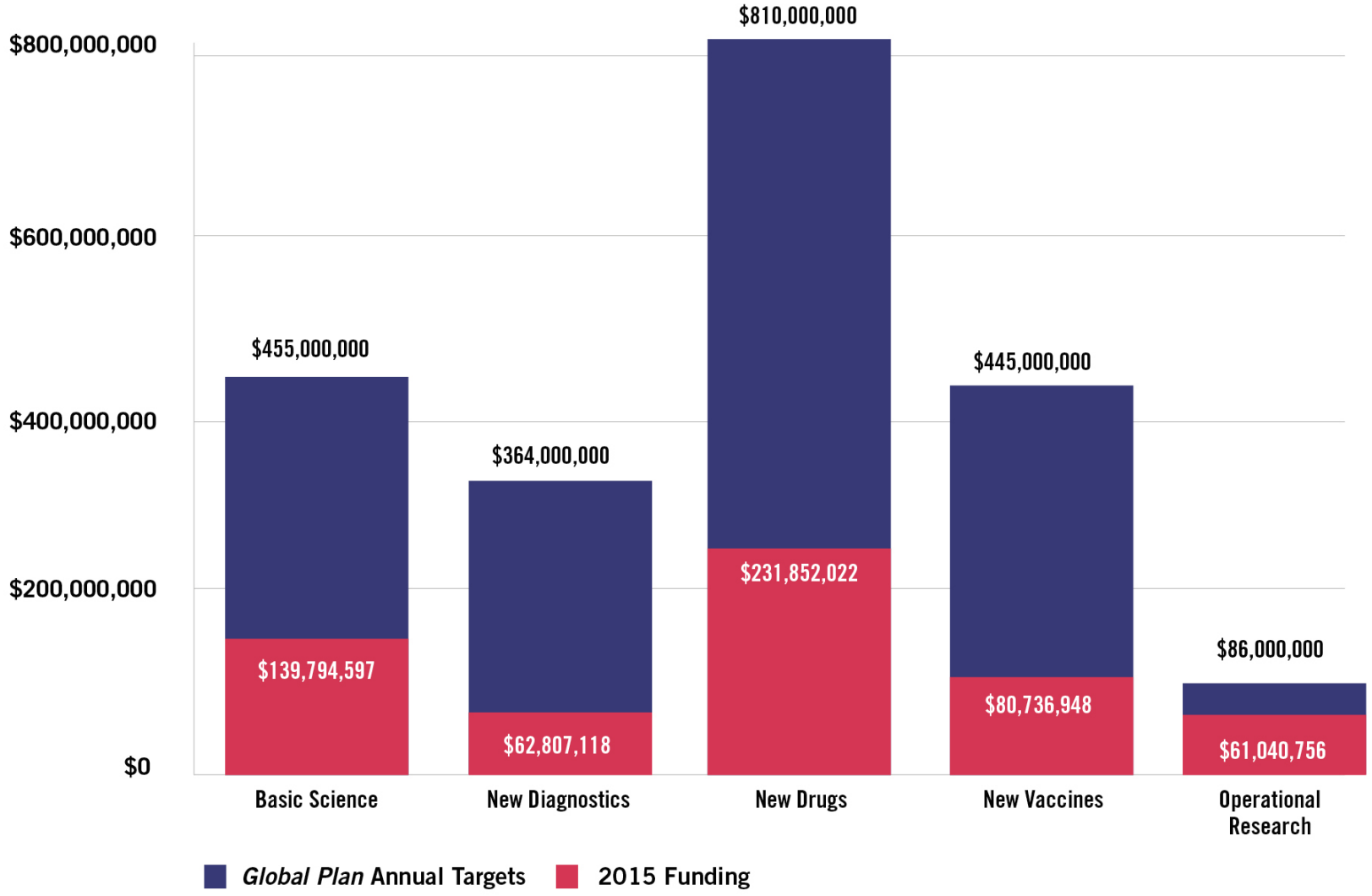
DIAGNOSTICS FUNDING:
HOW DID WE DO AGAINST
GLOBAL PLAN TO STOP TB FUNDING TARGETS?





http://www.treatmentactiongroup.org/tbrd2016

Annual *Global Plan* Research Funding Targets versus 2015 Funding



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TB Diagnostics R&D Progress Report

2011–2015 *Global Plan* Indicators of Success	Target (2015)	Reality (2015)
Number of new tests for the diagnosis of active TB that can be used in district labs	2	2
Number of new tests for active TB in peripheral labs	2	1
Number of new point-of-care tests for the diagnosis of active TB in peripheral health centers	2	1*
Number of new tests for the diagnosis of DR-TB in district labs	2	2
Number of new tests for the diagnosis of DR-TB in peripheral-level labs	1	0
Number of new tests for the diagnosis of DR-TB in health center	1	0
Number of new tests for LTBI and prediction of the risk of progression to TB disease	1	0**

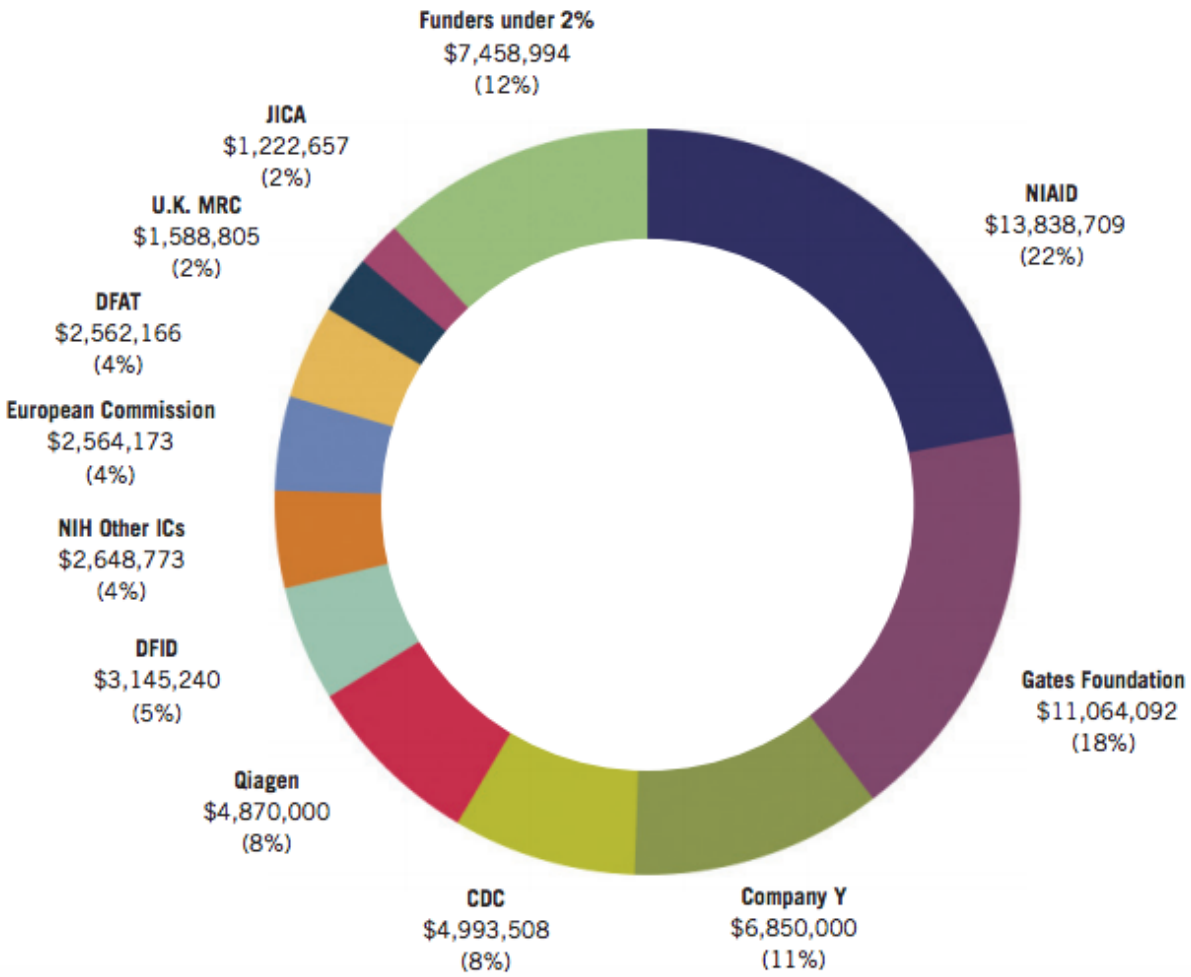
* Plus a negative recommendation against using serological tests (2011).

** Plus a negative recommendation against using IGRAs to predict progression from infection to disease (2011).

http://www.treatmentactiongroup.org/tbrd2016

DIAGNOSTICS FUNDING, 2015

Diagnostics: $62,807,118



<u>Diversity</u> matters, as well as <u>quantity</u>:

- **Over half of all diagnostics R&D funding comes from just 3 sources**
- **Extreme vulnerability to changes in priorities**

Source: http://www.treatmentactiongroup.org/tbrd2016

LACK OF FUNDING FOR TB R&D IS A HUMAN RIGHTS ISSUE

ICESCR Article 12	*The right to enjoy the highest attainable standard of physical and mental health*
ICESCR Article 15	*The right to enjoy the benefits of scientific progress and its applications*

TB research and access to its benefits…

1. **can either reinforce or resolve ethical dilemmas in TB prevention, <u>diagnosis</u>, treatment and care;**
2. **can change the way TB is culturally perceived;**
3. **can galvanize advocacy and clarify social or legal petitions for redress of TB-related harms.**

LIMITED FUNDING HAS HELPED GIVE RISE TO ETHICAL DILEMMAS FACED BY TB PROGRAMS

1 Weak R&D environment leaves people with TB and health systems reliant on diagnostics that are complicated, expensive, and difficult to access, or have low sensitivity.

2 Limitations to TB diagnosis and treatment—still unresolved by research—have changed the nature of TB disease itself, making the curable intractable.

1 Where inadequate and outdated tools hinder a vigorous public health response, fulfilling the Right to Health may require investing in R&D.

LIMITED FUNDING LIMITS THE EQUITY PROPOSITION OF TB RESEARCH FROM THE OUTSET…

…and means compromise is woven into the fabric of TB research itself.

1. ex: research that includes most vulnerable populations scarce – diagnosis for children still extremely challenging
2. ex: without a true POC diagnostic, equity is impossible for people living in rural areas / areas with worse health infrastructure
3. ex: given limited understanding of progression from TB infection to active disease, LTBI test and treat strategies cannot well distinguish those most at risk, leading to over- or undertreatment rather than equitable access to preventive therapy based on risk

WE CAN DO BETTER

"Essentially, there can be no End to TB, without an end to political indifference in this R&D agenda."

--Lynette Mabote, AIDS & Rights Alliance for Southern Africa

Closing the funding most likely needs to come from public sector

The *Global Plan to End TB* era features several important opportunities for raising political will for R&D funding

- **BRICS Declaration** Sep 2017: "*We agree to […] foster the development and improve the availability of innovative medical products through promotion of research and development and access to affordable, quality, effective and safe drugs, vaccines, diagnostics and other medical products and technologies*"
- **2017 Ministerial Conference**
- **2018 High Level Meeting on TB**

We will need ACCOUNTABILITY to ensure more than words

David Harrison for Treatment Action Campaign

WHILE R&D IS CRUCIAL, WE CAN DO MUCH BETTER WITH WHAT WE HAVE—

All Countries need:

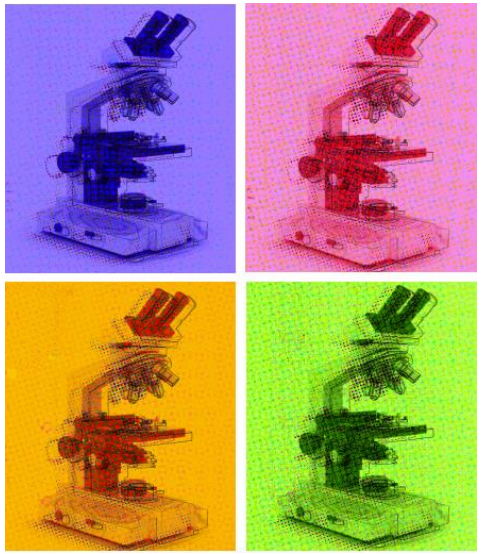
- **GeneXpert Xpert MTB/RIF ULTRA** as the initial test for ALL people needing testing for TB
- **Line Probe Assay (both first- and second-line)** to quickly guide treatment decisions
- **Liquid culture (MGIT)** for full drug susceptibility testing AND monitoring drug-resistant TB treatment
- **Smear microscopy** for monitoring drug-susceptbile TB treatment

In areas with high burdens of TB/HIV:

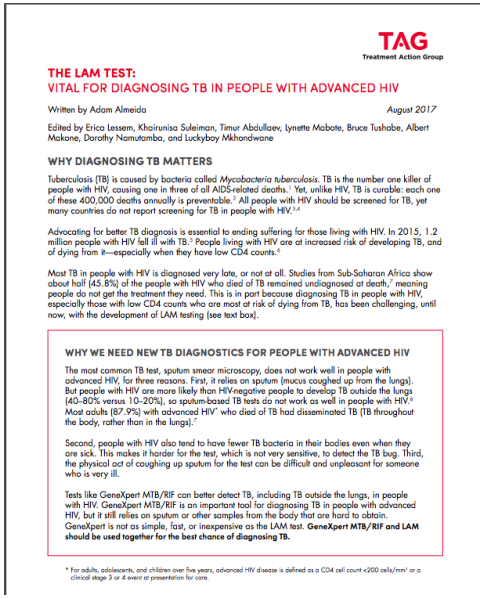
- **TB LAM (Determine TB LAM Ag)** for quickly, easily finding TB in people very sick with HIV and starting them on TB treatment

ADDITIONAL RESOURCES

Treatment Action Group (TAG) has created *An Activist's Guide to Tuberculosis Diagnostic Tools*: http://www.treatmentactiongroup.org/sites/default/files/TB%20Diagnostics%20Guide.pdf



TAG also issued *An Activist's Guide to the TB LAM Test,* available at:http://treatmentactiongroup.org/content/activists-guide-tb-lam-test



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THE LAM TEST:
VITAL FOR DIAGNOSING TB IN PEOPLE WITH ADVANCED HIV

Written by Adam Almeida *August 2017*

Edited by Erica Lessem, Khairunisa Suleiman, Timur Abdullaev, Lynette Mabote, Bruce Tushabe, Albert Makone, Dorothy Namutamba, and Luckyboy Mkhondwane

WHY DIAGNOSING TB MATTERS

Tuberculosis (TB) is caused by bacteria called *Mycobacteria tuberculosis*. TB is the number one killer of people with HIV, causing one in three of all AIDS-related deaths.[1] Yet, unlike HIV, TB is curable: each one of these 400,000 deaths annually is preventable.[2] All people with HIV should be screened for TB, yet many countries do not report screening for TB in people with HIV.[3,4]

Advocating for better TB diagnosis is essential to ending suffering for those living with HIV. In 2015, 1.2 million people with HIV fell ill with TB.[5] People living with HIV are at increased risk of developing TB, and of dying from it—especially when they have low CD4 counts.[6]

Most TB in people with HIV is diagnosed very late, or not at all. Studies from Sub-Saharan Africa show about half (45.8%) of the people with HIV who died of TB remained undiagnosed at death,[7] meaning people do not get the treatment they need. This is in part because diagnosing TB in people with HIV, especially those with low CD4 counts who are most at risk of dying from TB, has been challenging, until now, with the development of LAM testing (see text box).

WHY WE NEED NEW TB DIAGNOSTICS FOR PEOPLE WITH ADVANCED HIV

The most common TB test, sputum smear microscopy, does not work well in people with advanced HIV, for three reasons. First, it relies on sputum (mucus coughed up from the lungs). But people with HIV are more likely than HIV-negative people to develop TB outside the lungs (40–80% versus 10–20%), so sputum-based TB tests do not work as well in people with HIV.[8] Most adults (87.9%) with advanced HIV* who died of TB had disseminated TB (TB throughout the body, rather than in the lungs).[7]

Second, people with HIV also tend to have fewer TB bacteria in their bodies even when they are sick. This makes it harder for the test, which is not very sensitive, to detect the TB bug. Third, the physical act of coughing up sputum for the test can be difficult and unpleasant for someone who is very ill.

Tests like GeneXpert MTB/RIF can better detect TB, including TB outside the lungs, in people with HIV. GeneXpert MTB/RIF is an important tool for diagnosing TB in people with advanced HIV, but it still relies on sputum or other samples from the body that are hard to obtain. GeneXpert is not as simple, fast, or inexpensive as the LAM test. **GeneXpert MTB/RIF and LAM should be used together for the best chance of diagnosing TB.**

* For adults, adolescents, and children over five years, advanced HIV disease is defined as a CD4 cell count <200 cells/mm³ or a clinical stage 3 or 4 event at presentation for care.

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