

Demanding a Higher Standard of TB Care:

New tools, new challenges, new approaches to improving TB diagnosis

3 September 2020

Housekeeping

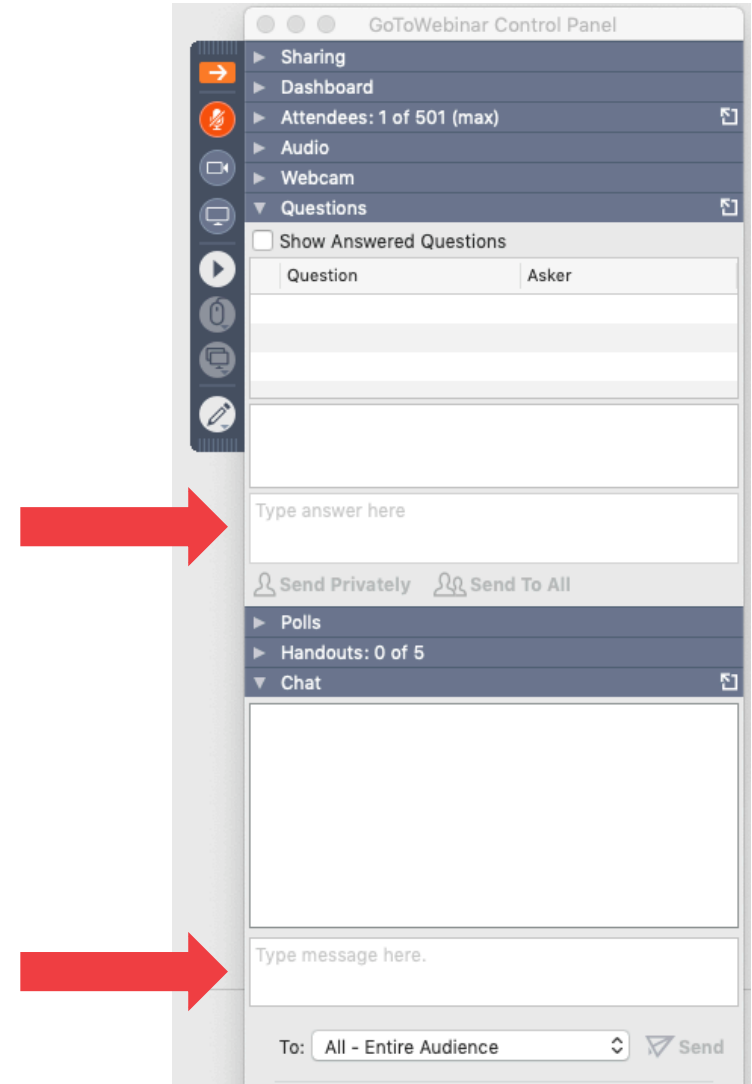
- Live captioning
- 1 hour 15 minutes
- 4 presentations (8-10 min each)
- Q&A segment (20-30 min)
- Please submit questions using “questions” or “chat” feature

Captioner: Darcy Kriens from ACS Captions

Caption Link:

<https://www.streamtext.net/player?event=TAG>

*Just click the link to open live captioning alongside webinar screen.



Part Two of Two-Part Series

Wednesday, Sept. 2nd @8:00 AM ET

Treatment for Drug-resistant TB

- **Introduction**, Lindsay McKenna, Treatment Action Group (TAG)
- **A Decade+ in the Making: All course Regimens for DR-TB**, Harvard Medical School
- **Mobilizing Resources and Improving Access**, Sharonann
- **DR-TB Cascade of Care & Proposed Solutions for Addressing Obstacles Faced by Affected Communities**, Paran Winarni, Pejuang Tangguh (PETA), Indonesia
- **Ensuring Access to the DR-TB Treatments of Today and Tomorrow**, Prathibha Sivasubramanian, Third World Network
- **Question and Answer Segment**, Facilitated by Lynette Mabote, Treatment Action Group (TAG)

Webinar slides and video available here soon!
<https://www.treatmentactiongroup.org/webinar/demanding-a-higher-standard-of-tb-care/>

Thursday, Sept. 3rd @8:00 AM ET

TB Diagnostic Tools

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- **Accessing Diagnostic Testing for TB and DR-TB at the Community Level: Challenges and Proposed Solutions**, Adebola Tope Adams, Nigeria TB People
- **The Highest Standard of Care for TB Diagnosis: The Tools We Have and How They Should Be Used Together**, Dr. Madhukar Pai, McGill University
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TAG

Treatment Action Group

Activist Guide Series

AN ACTIVIST'S GUIDE TO TREATMENT FOR DRUG-RESISTANT TUBERCULOSIS

TAG
Treatment Action Group

July 2020

Written by: Lindsay McKenna

Reviewed by: Christophe Perrin, Diptendu Bhattacharya, Gloria Kerubo Moses, Jennifer Furin, Jimmy Galarza Castillo, Lynette Mabote, Mike Frick, Oaxana Rucsieneanu, Sergey Kondratyuk, and Vivian Cox

I. INTRODUCTION AND BACKGROUND

In 2020, the World Health Organization (WHO) issued updated guidelines, establishing a new global standard of care for the treatment of **drug-resistant tuberculosis** (DR-TB).¹ The updated guidelines reinforce the use of standardized shorter regimens and move further away from the use of **injectable agents** (see box below) previously considered a cornerstone of treatment for drug-resistant TB.

The WHO first introduced guidelines supporting the use of a standardized shorter regimen for drug-resistant TB in 2016.² Over the course of several years, and in response to emerging evidence, the WHO modified the composition of the standardized shorter regimen it recommends under **program conditions**, replacing the injectable agent with bedaquiline.¹ In the latest iteration of its guidelines, the WHO also supports the use of other bedaquiline-based shorter regimens under **conditions of operational research** (i.e., the novel **Nix-TB regimen** and modifications to the standardized shorter regimen).³

The new global standard of care offers shorter, more effective, and less toxic treatment regimens. It also brings into clear focus what's at stake when people and communities affected by drug-resistant TB are unable to access the best available treatments—extended morbidity and time away from work resulting in lost income and financial instability, further development and transmission of drug-resistance, and increased risk of permanent disability and death.

We wrote this guide to help activists: unpack the latest WHO guidelines; understand the evidence behind each of the WHO-recommended regimens; identify barriers to availability, accessibility, and affordability; and hold governments and other actors accountable for ensuring all people and communities affected by drug-resistant TB can share in the benefits of scientific progress. This guide suggests actions activists can take to promote equitable access to the new global standard of care for drug-resistant TB.

KEY TERMS

DRUG-RESISTANT TUBERCULOSIS encompasses forms of TB resistant to key medicines (see section II).

PROGRAM CONDITIONS are the routine conditions under which National TB Programs operate and treat TB.

CONDITIONS OF OPERATIONAL RESEARCH require that National TB Programs monitor TB treatment more carefully than under program conditions and collect additional data on the safety and efficacy of medicines and/or treatment regimens not yet proven or endorsed for broader programmatic use, and for which additional research is needed.

the **NIX-TB REGIMEN** (also referred to as BPaL) is a six- to nine-month regimen composed of bedaquiline, pretomanid, and linezolid, and recommended by the WHO under very specific conditions (see section III).



Injectable agents, amikacin, kanamycin, capreomycin, and streptomycin, most of which are also referred to as aminoglycosides, were previously considered a key component of treatment for drug-resistant TB. These medicines, administered daily by injection, have toxic side effects that can cause permanent disability, including hearing loss, and kanamycin and capreomycin have been linked to increased risk of treatment failure and death. Another family of medications used to treat drug-resistant TB known as the carbapenems are also given via injection but are not routinely used and thus are considered as a separate category.

¹ Nine- to 12-months of clofazimine, levofloxacin (or moxifloxacin), ethambutol, and pyrazinamide; supplemented by bedaquiline for the first six months and high dose isoniazid, ethionamide (or prothionamide) for the first four- to six-months.

AN ACTIVIST'S GUIDE TO TUBERCULOSIS DIAGNOSTIC TOOLS

TAG
Treatment Action Group

July 2020

Written by: David Branigan

Reviewed by: Patrick Agbassi, Stijn Deborggraeve, Mikashmi Kohli, Blessina Kumar, Lynette Mabote, Emily MacLean, Albert Makone, Lindsay McKenna, Madhukar Pai, and Alexandra Zimmer

INTRODUCTION

Diagnosing tuberculosis (TB) is an essential step toward ensuring that all people with TB receive effective treatment and are ultimately cured of the deadly disease. While no TB diagnostic test is perfect, the technologies and tools used to diagnose TB continue to improve because of investments in TB research and development, making them more accurate, simple, and appropriate for use at the **point-of-care**. As TB diagnostic tools evolve, so do the recommendations and guidance from the World Health Organization (WHO) on how these tools should be optimally used in country programs. The following guide reviews current and forthcoming TB diagnostic tools and details the latest WHO guidance on the use of these tools.

All people at risk of TB have the right to TB diagnostic testing at the highest standard of care. In 2020, the United Nations Committee on Economic, Social, and Cultural Rights (CESCR) released a general comment on the right of all people to the benefits and applications of scientific progress. In the comment, the CESCR explained that an essential element of the right is “quality,” which it defined as “the most advanced, up-to-date and generally accepted and verifiable science available at the time, according to the standards generally accepted by the scientific community.”¹ The WHO is the primary body for determining the quality of TB diagnostic tools and for providing detailed policy recommendations and guidance on the optimal use and implementation of these tools. As part of this, the WHO keeps an essential diagnostics list (EDL) of WHO-recommended TB diagnostic tests that countries should prioritize and implement.² Yet, many countries have failed to fully scale up and implement TB diagnostic testing in accordance with WHO guidance and the EDL, thus failing to fulfill their human rights obligations under the **right to science** and the right to health.³

The TB diagnostic pathway is the entry point through which people with TB access the **TB cascade of care**. Under optimal circumstances, TB-affected communities are regularly offered TB screening and testing, followed by TB treatment or **TB preventive therapy (TPT)**⁴ as appropriate (see *Figure 1: The highest standard of care for TB diagnosis*). In actuality, however, many people seek care only after developing symptoms of active TB, and they often face stigma when doing so.^{5,6,7} Of those who are diagnosed, many do not receive the drug-susceptibility testing necessary to inform optimal treatment regimens. Meanwhile, low rates of TB preventive therapy (TPT) initiation persist among high-risk people, leaving them at risk of developing active TB disease.⁸

POINT-OF-CARE: the location where a person presents to care for a disease or condition

RIGHT TO SCIENCE: the right of all people to enjoy the benefits of scientific progress and its applications enshrined in Article 15 of the International Convention on Economic, Social and Cultural Rights

TB CASCADE OF CARE: the entire pathway of TB care, including diagnosis, treatment, and cure

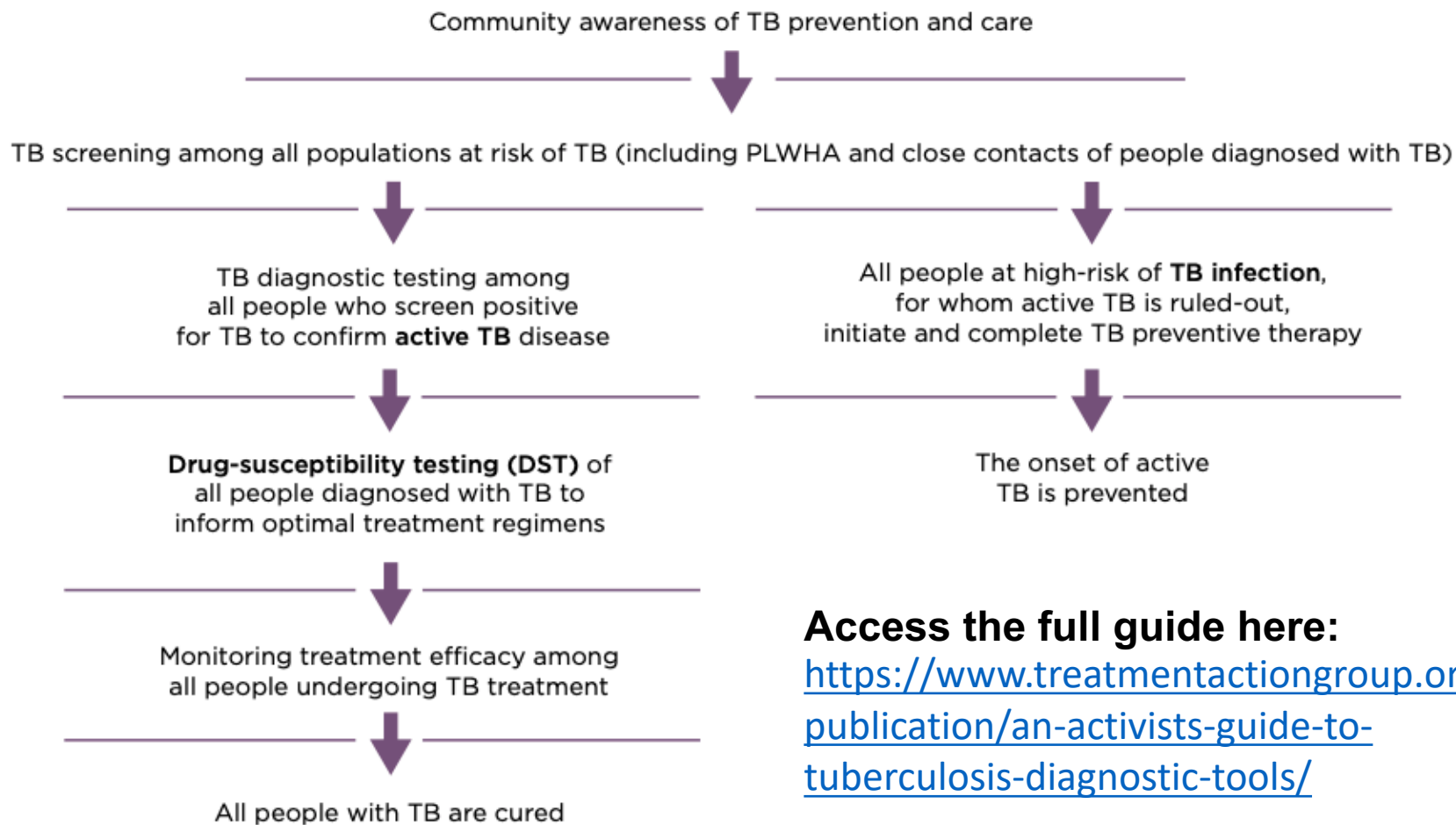
TB PREVENTIVE THERAPY (TPT): treatment taken by people with TB infection to prevent progression from infection to active TB disease; TPT is also sometimes given to protect people who are uninfected but at risk of TB exposure and infection

An Activist's Guide to Tuberculosis Diagnostic Tools

1. Reviews available tools for diagnosing active TB disease, including tools for TB screening, diagnosis, drug-susceptibility testing,* and treatment monitoring, as well as tools for detecting TB infection.
2. Describes how TB diagnostic tools should be used in country programs according to WHO recommendations in order to realize the highest standard of care for TB diagnosis, and the rights to health and science
3. Provides detailed tables with information on available TB diagnostic tools, including sensitivity and specificity, price per test, and corresponding WHO recommendation/s
4. Discusses access barriers to TB diagnostic testing (e.g., high prices and lack of price transparency, insufficient country uptake and implementation of tools, insufficient investment in the research & development and roll-out of new diagnostic tools)
5. Suggests actions activists can take to help overcome barriers and promote equitable access to quality TB diagnostic testing for all people at risk of TB

The latest WHO-recommended DR-TB treatment regimens are covered in-depth in *An Activist's Guide to Treatment for Drug-resistant Tuberculosis*.

The highest standard of care for TB diagnosis:



Access the full guide here:

<https://www.treatmentactiongroup.org/publication/an-activists-guide-to-tuberculosis-diagnostic-tools/>

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Treatment Action Group

Agenda Overview



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- **The Highest Standard of Care for TB Diagnosis: The Tools We Have and How They Should Be Used Together**, Dr. Madhukar Pai, McGill University
- **Translating Policy into Practice: Scaling Up Rapid Molecular Tests as the Initial TB Test for All & LAM Testing among PLWHA**, Stijn Deborggraeve, MSF Access Campaign
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Accessing Diagnostic Testing for TB and DR-TB at the Community Level: Challenges and Proposed Solutions

Adebola Temitope Adams

DR-TB Survivor / Advocate

TB PEOPLE, Nigeria



The importance of TB diagnostic testing

On treatment:

- It determines the extent/degree of illness/sickness.
- It enhances the effectiveness of the course of medical treatment.
- It ensures avoidance/stoppage of the wrong medication.

On people:

- It secures lives, finances, job opportunities, marriages.
- It reduces dependence on relatives.
- It reduces the high cost of treatment.
- It saves time.

My diagnostic journey

March 2004: Chest X-ray (Private clinic)

August 2004: Acid-fast bacilli (AFB) smear microscopy (DOTS centre)

August 2006: Chest Xray (Private clinic)

March 2007: AFB smear microscopy (DOTS centre)

August 2008: Samples sent to Belgium (DOTS centre)

May 2009: Samples sent to Abuja for culture (Private clinic)

June 2010: AFB smear microscopy (DOTS centre)

July 5, 2010 - February 7, 2011: admission into the MDR-TB ward based on the results of the samples sent to Belgium in 2008

Challenges to accessing TB diagnostic testing

- Stigma
- Low level/Lack of awareness
- Inadequate TB diagnostic testing centres
- Transportation issues
- Insufficient attention on the part of major stakeholders such as the government
- Poor engagement with/involvement of associations at the community level

Proposed solutions

Governments in collaboration with civil society/not-for-profit/non-governmental organisations should:

- Strengthen Ministries of Health to better address issues of TB diagnosis, treatment, management, and prevention
- Educate the public through digital and print media to raise awareness around TB symptoms and to reduce stigma
- Engage all stakeholders in the community with information and training to facilitate rapid referral for TB diagnostic testing
- Procure TB diagnostic tests that can be performed close to the point of care (e.g. Truenat)
- Provide financial and other social support to people who test positive for TB/DR-TB
- Establish national help-lines for people to get information on TB and how to access TB services

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The Highest Standard of Care for TB Diagnosis:

Tools We Have and How They Should Be Used Together

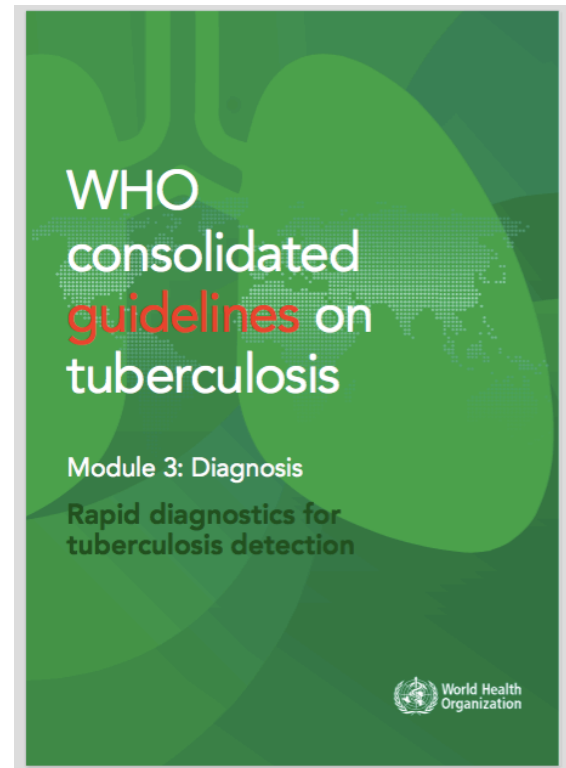
Madhukar Pai, MD, PhD

Director

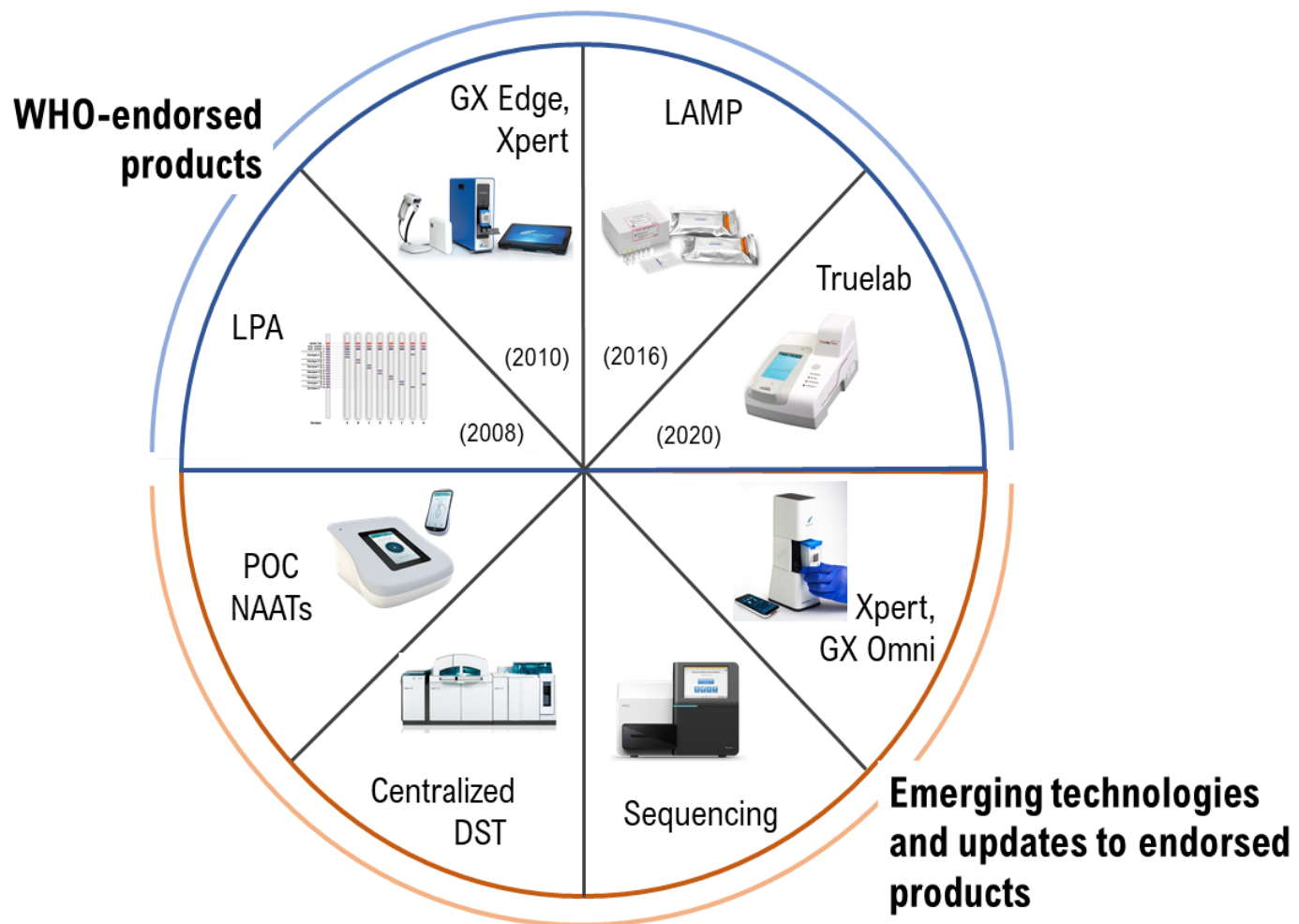
McGill International TB Centre

WHO-endorsed tests

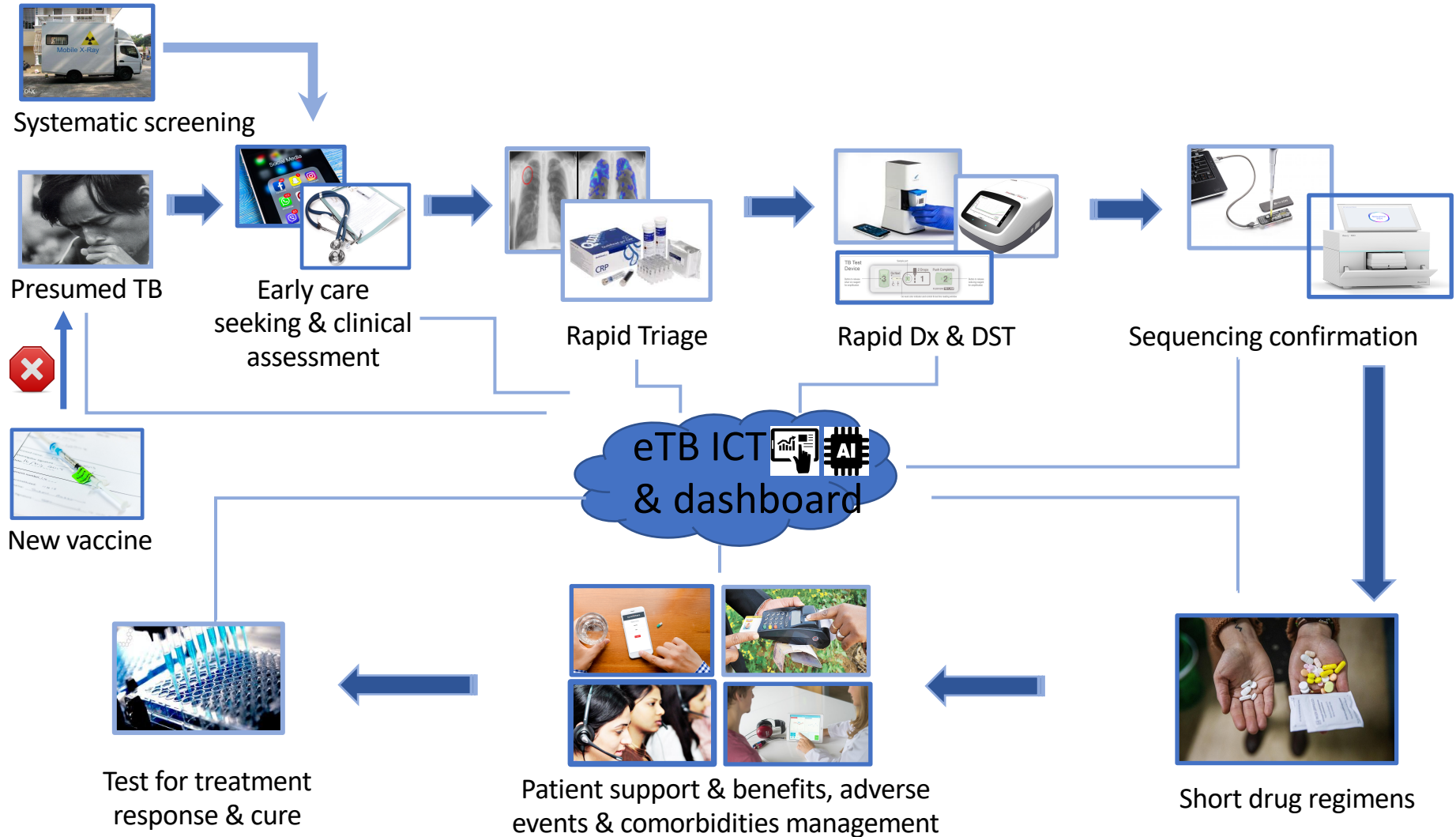
- Recently updated guidelines for various tools:
 - Liquid cultures: MGIT
 - Rapid molecular: Xpert MTB/RIF, Xpert Ultra and Truenat™
 - Line probe assays (LPAs)
 - TB-LAMP
 - Lateral flow assay: TB LAM
 - Latent TB infection: PPD & IGRAs



[WHO consolidated guidelines on TB: Module 3](#)



We can re-imagine TB care today



But, slow uptake of new tests

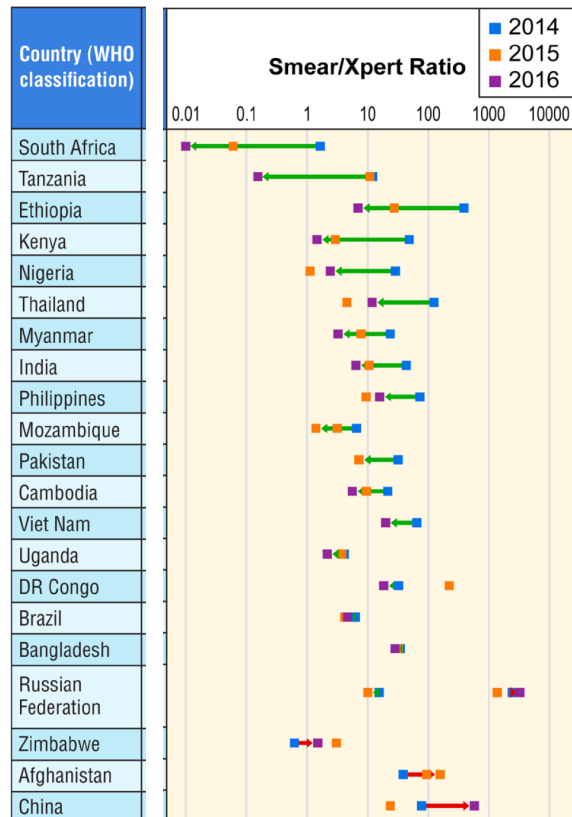


Table 1. Stages of implementation of Alere-LAM urine test by country.

Country	Does the country have policies that include Alere-LAM? (year of introduction) ^a	Which National Program includes Alere-LAM? (TB, HIV, both) ^b	Is Alere- LAM currently in use? ^c	Is Alere-LAM use planned for the near future? (prospective year) ^d
Angola	No	-	No	Yes (2019)
Botswana	Unclear ^a (2018)	TB	No	Yes (2019)
Brazil	No	-	No	Yes
Cameroon	-	-	No	Yes
CAR	Yes (2016)	Both	No	Yes (2019)
Chad	Yes (2018)	TB	No	Yes
China	No	-	No	No
DRC	No	-	Yes	Yes
Ethiopia	Yes (2017)	Both	No	Yes
Ghana	No	-	No	Do not know
Guinea-Bissau	No	-	No	No
India	Yes ⁱ	HIV	No	Yes (2020)
Indonesia	No	-	No	Yes
Kenya	Yes (2019)	Both	No	Yes
Malawi	Yes (2017)	Both	Yes	-
Mozambique	No	-	-	-
Myanmar	Yes (2017)	HIV	Yes	Yes
Nigeria	No	-	-	Yes (2019)
Philippines	No	-	No	Yes (2021)
Tanzania	No	-	No	No
Thailand	No	-	No	No
Uganda	Yes (2017)	Both	Yes	-
Zambia	Yes (2018)	TB	No	Yes
Zimbabwe	Yes (2017)	Both	Yes	-
Number answering "yes"	10	NA	5	15

Better Therapies For TB Are Here, But They Will Not Deliver Themselves

Forbes



Madhukar Pai Contributor

Healthcare

I write about global health, infectious diseases, and equity

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A pharmacist holds two sets of pills in her hands, showing the difference between the amount of... [+] GETTY

<https://www.forbes.com/sites/madhukarpai/2019/08/15/better-therapies-for-tb-are-here-but-they-will-not-deliver-themselves/#59081020272c>

Devastating impact of Covid-19

COVID-19 Coronavirus And Tuberculosis: We Need A Damage Control Plan



Madhukar Pai Contributor ©
Healthcare

I write about global health, infectious diseases, and equity

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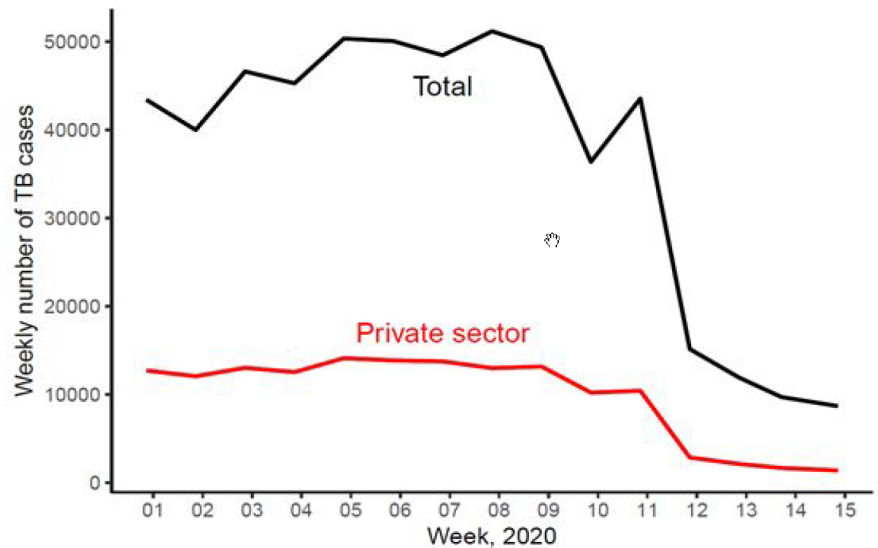


Figure 1. Trends in weekly case notifications in India in 2020

Forbes

Glaziou P. <https://www.medrxiv.org/content/10.1101/2020.04.28.20079582v1>

If we are not proactive

Stop TB Partnership

COVID-19 related
disruptions to
TB services
could lead to

6.3

million

additional people
developing TB

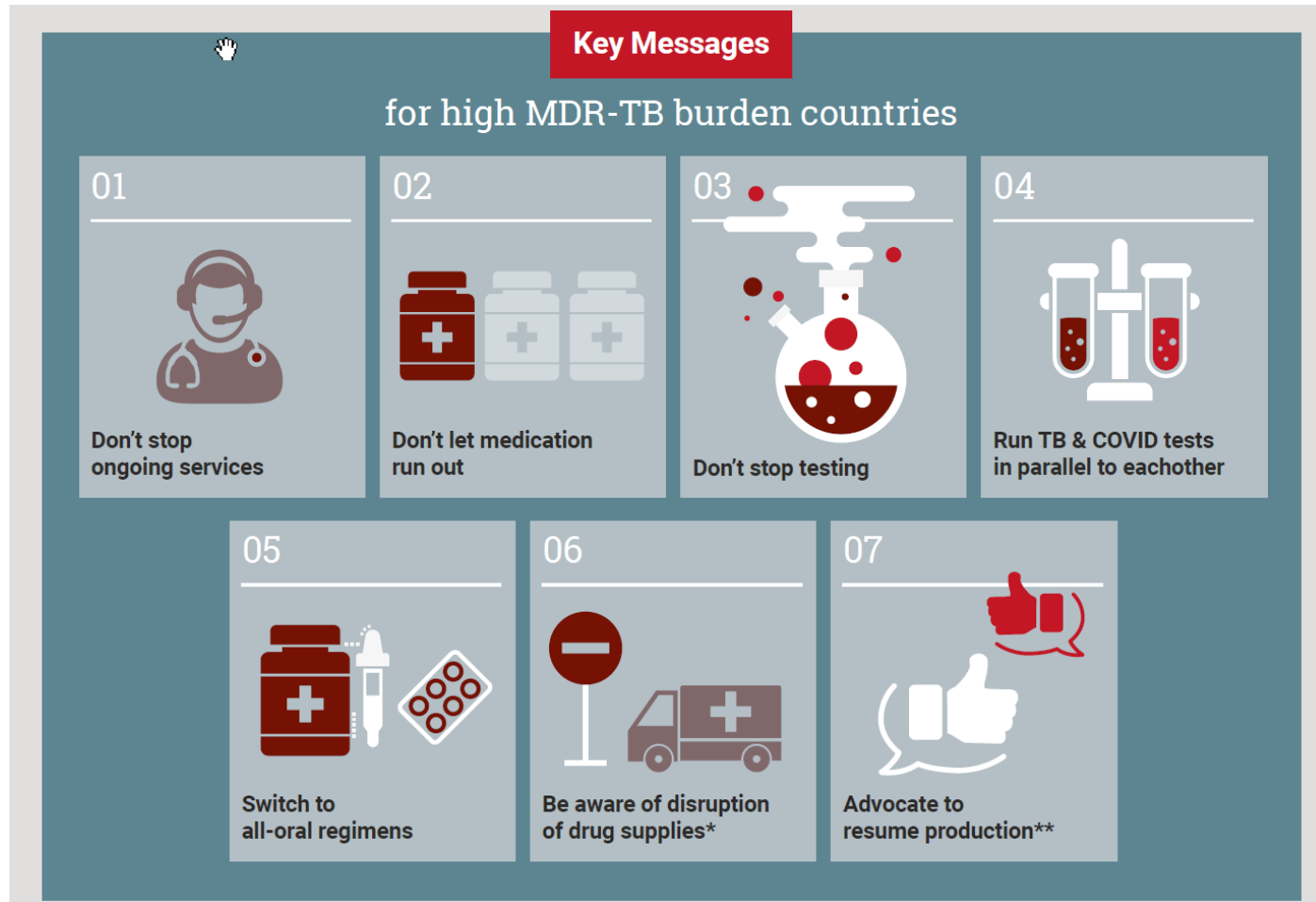
1.4

million

additional
TB deaths

by 2025

Here is how we can mitigate the damage



Source: Global TB Caucus, McGill International TB Centre, TB PPM Learning Network

<https://www.globaltbcaucus.org/mdr-tb>

Integrate Covid-19 and TB testing

- Since both diseases have similar symptoms
- Multi-disease platforms & same sample (ideally)
- Will require massive expansion of molecular dx
- Dx companies must not de-prioritize TB tests



Cepheid Xpert MTB/RIF and Xpress SARS-CoV2



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Translating Policy into Practice:

Scaling Up Rapid Molecular Tests as the Initial TB Test for All & LAM Testing among PLWHA

STIJN DEBORGGRAEVE

MSF ACCESS CAMPAIGN



WHO recommendations (2020)



**Xpert MTB/RIF
Xpert MTB/RIF Ultra**

Should be used
Initial test for all
Signs of TB and EPTB



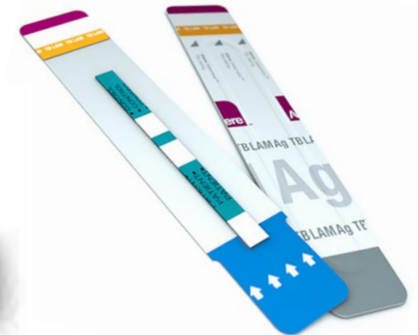
**Truenat MTB (Plus)
Truenat MTB/RIF Dx**

May be used
Initial test for all
Signs of TB



LAMP

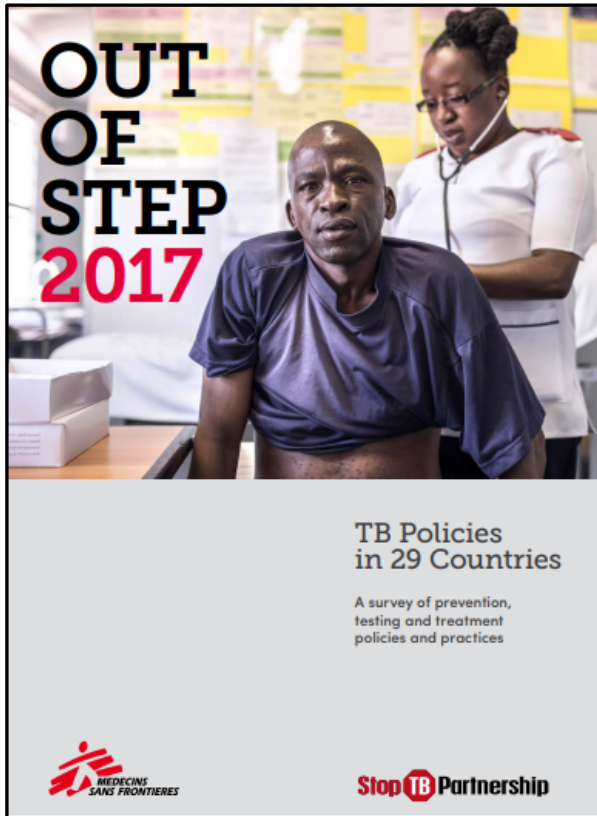
May be used
Replace microscopy
Signs of TB



TB LAM

Recommended
PLWHA
Inpatients
- Signs of TB/EPTB
- AHD
- CD4 <200
&
Outpatients
- Signs of TB/EPTB
- CD4 <100

Adoption by national policies

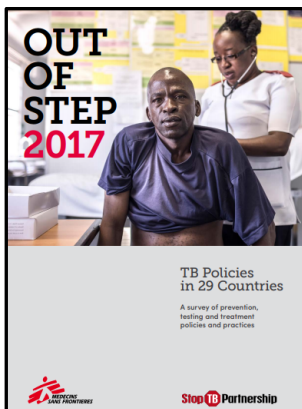


**STEP
UP
FOR
TB
2020**

TB Policies
in 37 countries

Will be released soon

https://msfaccess.org/sites/default/files/MSF_assets/TB/Docs/TB_Report_OutOfStep_3rdEd_ENG_2017.pdf



52% countries recommend Xpert MTB/RIF as initial test for all

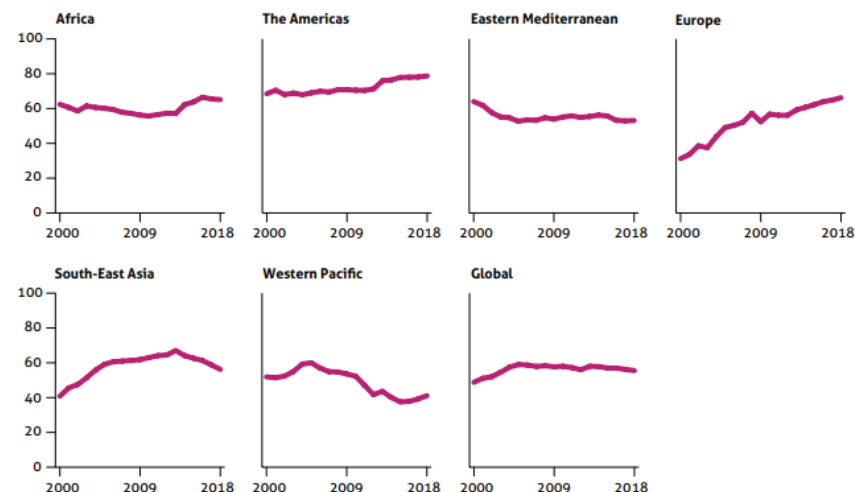
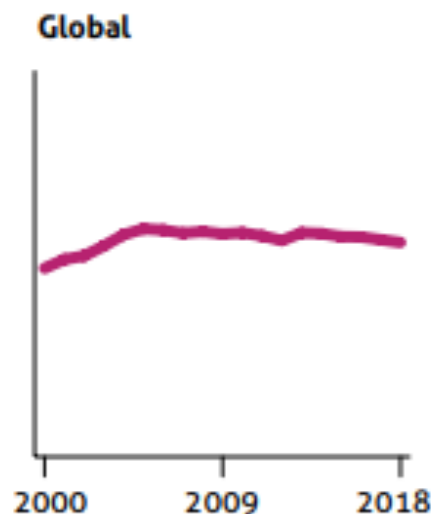
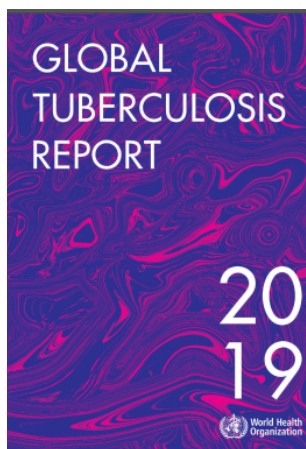
40% countries with Xpert for all policy have made the test widely available

7% countries recommend TB LAM for PLWHA

0% have made the test available

Singhroy et al. 2020

46% recommend TB LAM for PLWHA
less than half make the test available



Percentage of new and relapse^a pulmonary TB cases with bacteriological confirmation, globally and for WHO regions, 2000–2018

WHAT WE SHOULD DO

COUNTRIES

- **RMD for all at all health care levels, including specimen referral**
- **TB LAM adoption in TB & HIV policies, GF & PEPFAR proposals**
- **TB LAM in inpatient and outpatient settings, and at PHC level**
- **Community advocacy to demand RMD & TB LAM scale up**

STAKEHOLDERS

- **Adequate funding of countries for implementation and scale-up**
- **Clear recommendations and guidance for country adoption**
- **Monitor diagnostic coverage and support where needed**

COMPANIES

- **Ensure affordable RMDs, including service and maintenance**
- **Support countries in scale up & transition to new technologies**
- **More sensitive TB LAM tests**
- **Should not displace TB test production and R&D for COVID**

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Opportunities and Challenges for TB Diagnostics Advocacy in the Context of COVID-19: Holding Actors Accountable & Mobilizing Political Will for Action

BLESSINA KUMAR

THE GLOBAL COALITION OF TB ACTIVISTS

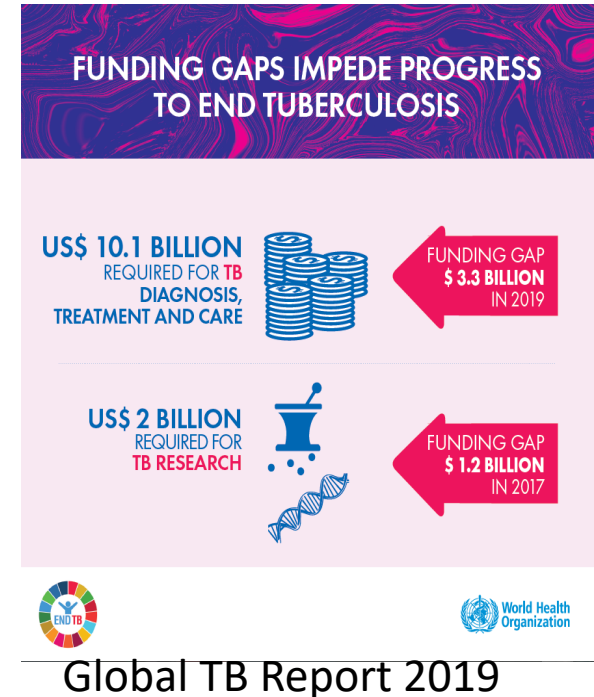


3rd September 2020

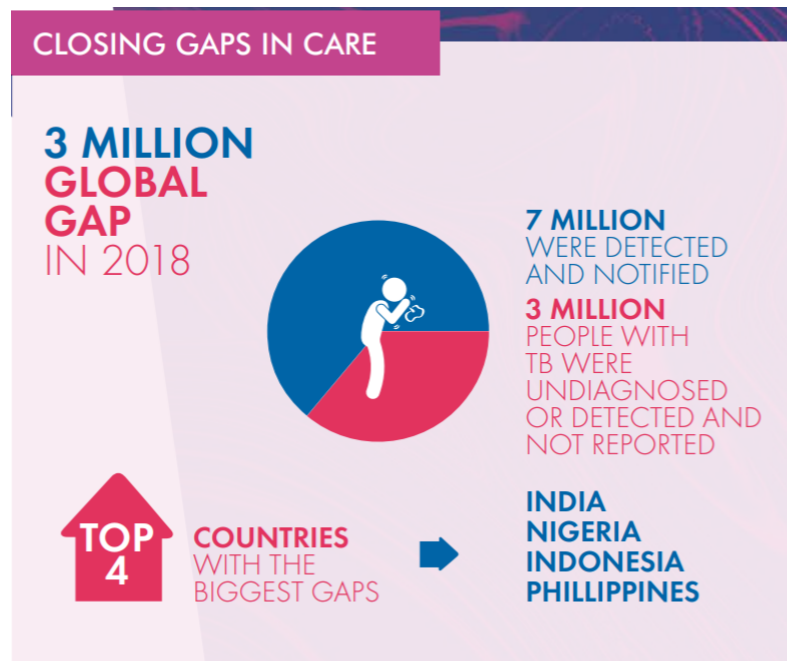
Starting off on a weak footing!

Challenges: Global funding Gap for TB

- There's a global funding gap of **US\$ 3.3 Billion** for TB (Global TB Report – 2019, WHO)
- Top 3 underfunded regions (The Global Plan to Stop TB) Africa, Eastern Europe, South East Asia
- In Global Fund countries an additional **US\$7.4 billion** must be mobilized for countries to reach the 2020 milestones (Tuberculosis Information Note - 2019, Global Fund)
- Estimated total funding gap of **US\$22.5 billion** country level over the next 10 years.



Challenges: TB Diagnosis in High Burden Countries



Global TB Report 2019

In 2018, 3 Million people with TB were undiagnosed or detected and not reported

Challenges: TB Diagnosis

Survivors speak –

- In trainings conducted in Asia pacific, Latin America, Africa and India with 187 survivors representing 28 countries, identified getting the right diagnosis as a huge challenge in the cascade of care– **lack of information, stigma and costs** top the list as barriers
- Lack of knowledge of doctors
- Wrong diagnosis
- Non availability of staff at labs

Challenges/ Impact: Covid- TB

- First early stage community survey by GCTA- Lockdown, transport, fear, non availability of Health staff, redirection of staff and resources, non functioning Health Centers, Nutrition and other social support
- Recent CS and Community Survey – Different stakeholders, over 1000 respondents, responses more in the middle of COVID-19- Report will be launched on 15th September
- While stringent COVID-19 responses may only last months, they would have a lasting impact on TB in high-burden settings, through their effect mainly on TB diagnosis and treatment (STB Modeling Report)

Indicator	Reason for effect	India	Kenya	Ukraine
<i>From initiation of lockdown</i>				
Probability of diagnosis per visit to a provider	Reduced lab capacity and availability of healthcare staff	Drops by 70%	Drops by 70%	Drops by 50%

- Additional **6.3 million** cases of TB and **1.4 million deaths** between 2020 and 2025
- Setback of at least **5-8 years** in the fight against TB
- Already neglected **TB pushed back** even further

Challenges/ Impact: Covid- TB Diagnostics

- 'All diagnostic companies redirecting attention and product capacity to Covid -19 tests'
- Diversion of resources through repurposing of existing tests and platforms – June 2020 Lancet article 'Covid not at the expense of other diagnostics'
- Large decrease in case finding
- Supplies being disrupted
- Health centers not functioning fully

TB- COVID- Opportunities- Advocacy Push-Pull!

- **Accessibility**- where are the diagnostics available in countries
- **Availability?** Stock outs of cartridges, staff, Public health information?
- **Acceptability?** Dignity and respect, No stigma
- **Affordability?** cost? –diagnosis and out of pocket, loss of wages, fair pricing- related to COGS
- **Appropriate?** WHO approved diagnostics made available? Or are we still using smear microscopy? LAM?

It's a question of Rights!- Human Rights- Right to science and Right to Health

TB- COVID- Opportunities- Advocacy

- CS groups have written to Health Ministers Presidents and NTPs re effects of COVID response on TB, TB/HIV during the pandemic
- CS has also advocated and pushed back on high pricing –
- Most patent oppositions are by CSOs and community orgs.
- Use real time data on ground realities reported by CS and communities
- Support – provided by community groups on the ground – linking for diagnostics, getting appointments, letters of referrals, arranging transportation, social support etc
- 2019 Time for \$5 campaign –Cepheid to lower the price of Xpert test for TB and other diseases

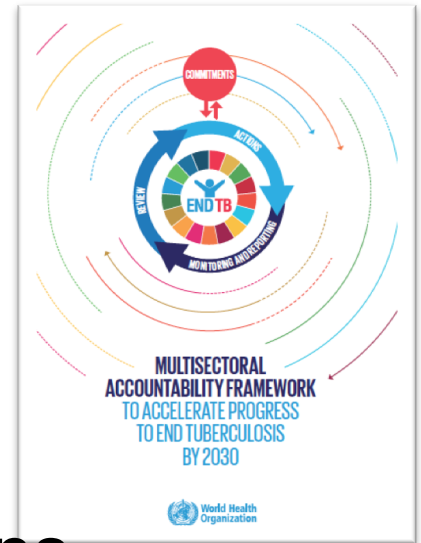
TB- COVID- Opportunities- Advocacy

Opportunities

- Political will
- National Programs- driven by COVID nos.
Real time data eg. Daily deaths
- R&D
- Information/ Attention/ messaging- mask/
hands/distance
- Addressing barriers to access
- Bi-Directional testing for TB and Covid- India
Sept 2020

Accountability

- **MAF Indicators, JMM, Program reviews, CLM, Shadow Reports, Stakeholder Surveys**



Covid-Daily data/ numbers- new infections, deaths, recoveries, geographical distribution, response to the numbers

Data drives the response!

Civil Society and Communities are best placed to hold Actors accountable

- Strength in numbers
- Pressure points for different actors

Accountability

Countries, NTPs – Maintain TB testing services

Donors- No shifting focus from TB

Companies- ‘No profits over lives’

R&D- for Covid must not be at the cost of TB

‘No compromise on Quality of care! No more window dressing’

Agenda Overview



Thursday, Sept. 3rd @8:00 AM ET

TB Diagnostic Tools

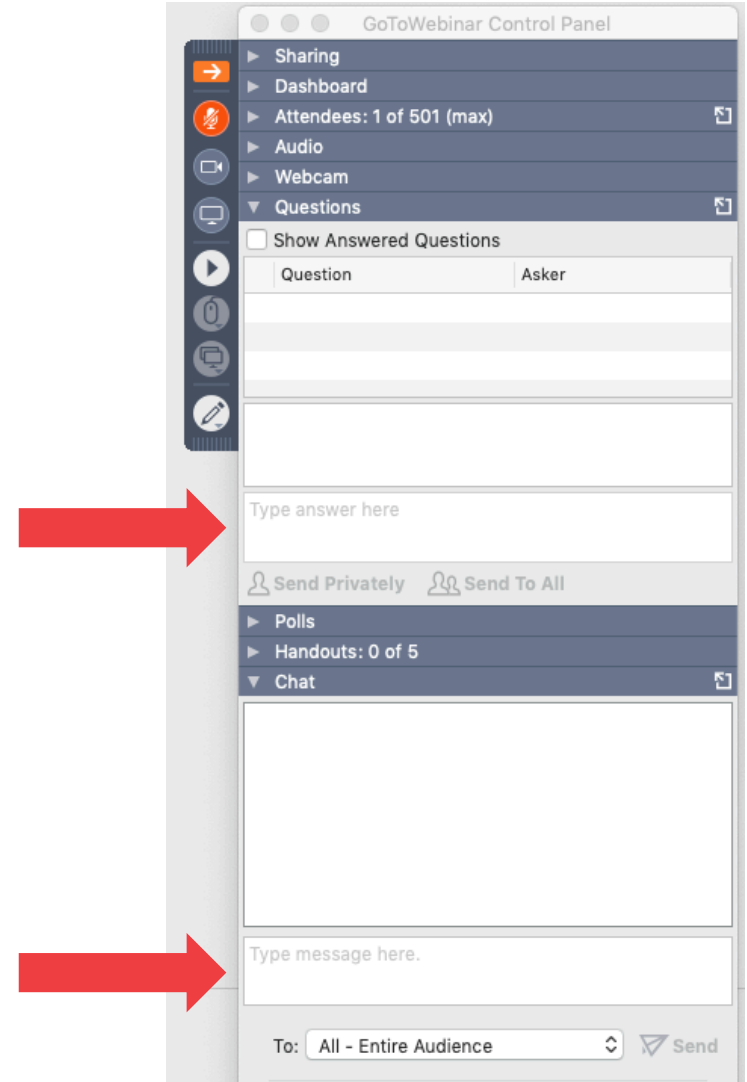
- **Introduction**, David Branigan, Treatment Action Group (TAG)
- **Accessing Diagnostic Testing for TB and DR-TB at the Community Level: Challenges and Proposed Solutions**, Adebola Tope Adams, Nigeria TB People
- **The Highest Standard of Care for TB Diagnosis: The Tools We Have and How They Should Be Used Together**, Dr. Madhukar Pai, McGill University
- **Translating Policy into Practice: Scaling Up Rapid Molecular Tests as the Initial TB Test for All & LAM Testing among PLWHA**, Stijn Deborggraeve, MSF Access Campaign
- **Opportunities and Challenges for TB Diagnostics Advocacy in the Context of COVID-19: Holding Actors Accountable & Mobilizing Political Will for Action**, Blessina Kumar, Global Coalition of TB Activists (GCTA)
- **Question and Answer Segment**, Facilitated by Lynette Mabote, Treatment Action Group (TAG)



Question & Answer Segment

Please submit your questions using
“questions” or “chat” feature.

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4. TAKING ACTION: DEMAND ACCOUNTABILITY AND ACTION

This Activist's Guide provides information on the optimal use of TB diagnostic tools and how these tools should be implemented in health systems to realize the highest standard of care for TB diagnosis. It also highlights critical gaps in the uptake and implementation of TB diagnostic tools and identifies barriers that limit access to quality TB diagnostic testing. Removing these barriers to access and closing the TB diagnostic gap requires accountability and action from country governments, global donors, and diagnostics companies. Activists can demand this by:



Calling on country governments to:

- increase funding for TB research and development (R&D) to meet or exceed fair share funding targets,¹⁴⁷ and include conditions of cost-of-goods-sold (COGS) transparency and fair pricing—reflective of COGS, volumes, and public and philanthropic investments—as part of all R&D funding agreements with TB diagnostics developers;
- increase domestic funding for health and expand TB budgets to sufficiently invest in strengthening national health systems—including laboratory infrastructure and capacity—and fully scaling-up and implementing quality TB diagnostic tools in accordance with WHO recommendations, while engaging in pooled procurement with other countries and global donors to secure TB diagnostic tools at the lowest possible prices through shared volumes; and
- update national TB and HIV program policies and implementation guidelines in accordance with new WHO recommendations, and establish clear plans for the rapid introduction, scale-up, and implementation of WHO-recommended TB diagnostic tools and algorithms, including through countrywide training of health workers and lab technicians in the use of new diagnostic tools and technologies.

2**Calling on global donors to:**

- increase funding for the R&D of new TB diagnostic tools, and include binding access commitments requiring COGS transparency and fair pricing as a condition of R&D funding;
- increase funding support for countries to invest in the introduction, full scale-up, and implementation of quality TB diagnostic tools in accordance with WHO recommendations; and
- coordinate together and with countries to apply collective procurement power and leverage toward negotiating lower prices for TB diagnostic tools reflective of COGS, volumes, and public and philanthropic funding, and invest in building regional and country know-how and capacity—including through technology transfer—for generic diagnostics manufacturing.

3**Calling on diagnostics companies to:**

- invest in the R&D of new TB diagnostic tools in line with the WHO target product profiles and engage communities—including community advisory boards (CABs)—to inform design and access considerations in the early stages of the development of these new tools;
- commit to transparency and fair pricing structures and work with governments, global donors, and other actors to develop prices that transparently reflect COGS, volumes, and public and philanthropic investments; and
- ensure that new TB diagnostic tools are accessible in all countries with high burdens of TB, that service and maintenance plans—if applicable—are effective and priced equitably and affordably, and that sufficient manufacturing capacity is in place to reach volumes that fully meet the supply and pricing needs of all high-TB-burden countries.

THANK YOU !

The slides and videos of the webinars in this two-part Activist's Guide series "*Demanding a Higher Standard of TB Care*" will be available soon at:

<https://www.treatmentactiongroup.org/webinar/demanding-a-higher-standard-of-tb-care/>.