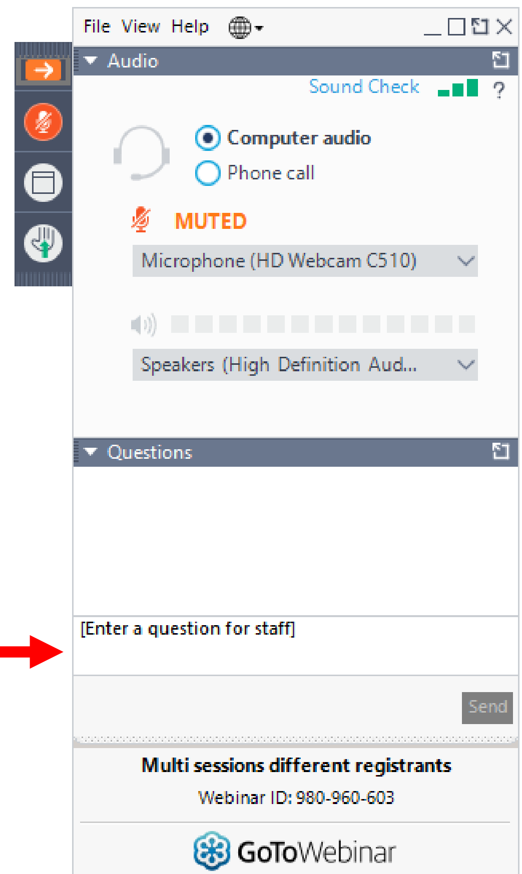
Good COPs or Bad COPs 2.0

Advocacy to Ensure the Prioritization of TB in 2019 PEPFAR Country Operational Plans (COPs)

January 23, 2019

Webinar Instructions

- **Audience is "listen-only" mode**
- **To ask questions, use the chat feature**



Agenda

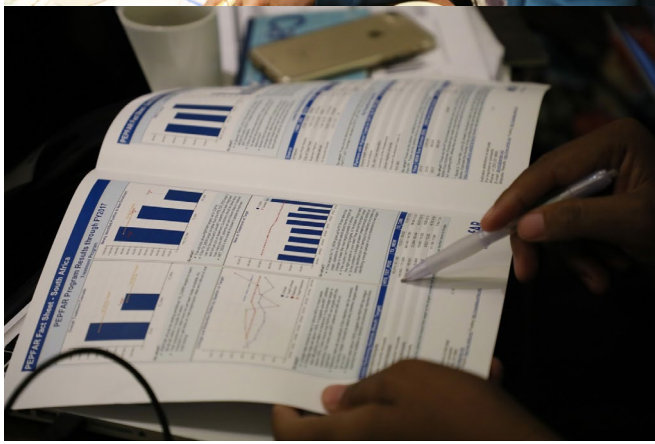
- **Overview of importance of PEPFAR COPS and advocacy on TB** – Lotti Rutter, Associate Director, International Policy and Advocacy, Health GAP
- **TB Preventative Therapy** - Lynette Mabote, Health Activist and Consultant
- **Diagnostics: LAM, Xpert, CXR** – Albert Makone, Public Health Consultant and Health Activist
- **Pediatric TB** – Martina Casenghi, CaP TB Project Technical Director, Elizabeth Glaser Pediatric AIDS Foundation
- **Q&A** – moderated by Lotti
- **Tools, resources, closing**

TAG
Treatment Action Group

Influencing and Monitoring PEPFAR Country Programs

What is the PEPFAR COP?

- Every year, PEPFAR engages in a planning process to create a Country Operational Plan (COP) for each major country that receives funding.
- Set out PEPFAR's strategy for the following year (COP19 will decide what happens during the budget year Sept 2019-Oct 2020)
- Sets targets that country teams & implementers will be tasked with meeting (e.g. New people on treatment, KPs reached)
- Sets budget allocation (e.g. how much for treatment? PrEP? Etc.)
- Sets geographic focus
- Includes policy language on key activities (like how many health workers will be paid, whether PrEP will be part of Dreams, etc.)



Why should activists care?

PEPFAR is a dominant source of funding for HIV programs and health systems strengthening in many countries.

As TB is the leading global killer of people living with HIV, TB programming must be prioritized and integrated within life-saving bilateral efforts such as PEPFAR.

It is critical that PEPFAR funding is put to the best possible use, in accordance with community needs.

The COP process provides a critical opportunity for activists to ensure that the latest developments in TB treatment, prevention and diagnostics are implemented within PEPFAR countries.

What can activists change? (2018 wins)

•In **South Africa**, a commitment to fund over 20,000 additional health workers including nurses, pharmacists, and a tripling of the number of PEPFAR-funded community health workers.

•In **Malawi**, a bold new commitment to support viral load testing for all people living with HIV (PLHIV) in the country in 2019 and a major new “undetectable” campaign.

•In **Kenya**, scale up of support for key population-led organizations to provide service delivery to increase testing and retention and an increase in the number of comprehensive care clinics for key populations.

•In **Uganda**, a $234,000 COP 2018 investment in a groundbreaking harm reduction service delivery program.

•In **Mozambique**, an expansion of funding into direct service delivery, resulting in an additional $8 million for healthcare and laboratory staff and an additional $5.95 million for community health workers.

•In **Tanzania**, funding of more than 10,000 community health workers, an increase in MSM targets, commitments to fund community led treatment literacy efforts.

Key moments in COP Activist Calendar

When?	What happens?	What can activists do?
January 2019	The formal PEPFAR process begins	This is the time to identify your priorities for change. Build a written priority list.
January 28 - February 1 2019	PEPFAR teams in each country have a "strategic retreat."	In person meeting for analysis of the docs shared in last slide and Q4 data and focus on solutions that will form basis of COP19 – they will share other data and results
March 4-8 (Group 1) **March 11-15** (Group 2) **March 18-22** (Group 3)	**COP19 Meetings (Johannesburg)**: PEPFAR country & Washington D.C. teams, local and international civil society groups, representatives from recipient country governments, UNAIDS and Global Fund gather in Johannesburg for five-day meetings where they will lay out the priorities.	This is a key advocacy moment where civil society can influence what PEPFAR funds. **Group 1:** Burundi, Ethiopia, Kenya, Malawi, Rwanda, South Sudan, Tanzania, Uganda **Group 2:** Botswana, Lesotho, Mozambique, Namibia, Angola, South Africa, Eswatini, Zambia, Zimbabwe **Group 3:** Cameroon, Côte d'Ivoire, Democratic Republic of the Congo, Haiti, Dominican Republic, Nigeria, Ukraine, Vietnam, West Central Africa

When?	What happens?	What can activists do?
March 2019	Country Operational Plan is drafted	What was decided in Johannesburg in March is only the first step and many details still have to be worked out including the exact activities, budgets, and areas of geographic focus.
March 29, 2019 (Group 1) **April 5, 2019** (Group 2) **April 12, 2019** (Group 3)	**COPs due** to the Office of the Global AIDS Coordinator (PEPFAR's Headquarters) in Washington, D.C.	After COP submission, the work is not over. You can still influence by lobbying the PEPFAR teams.
April 15-25, 2019 (all groups)	**Virtual COP approval**	Ambassador Birx will officially decide whether to sign and approve the COP or not

Join PEPFAR Watch!

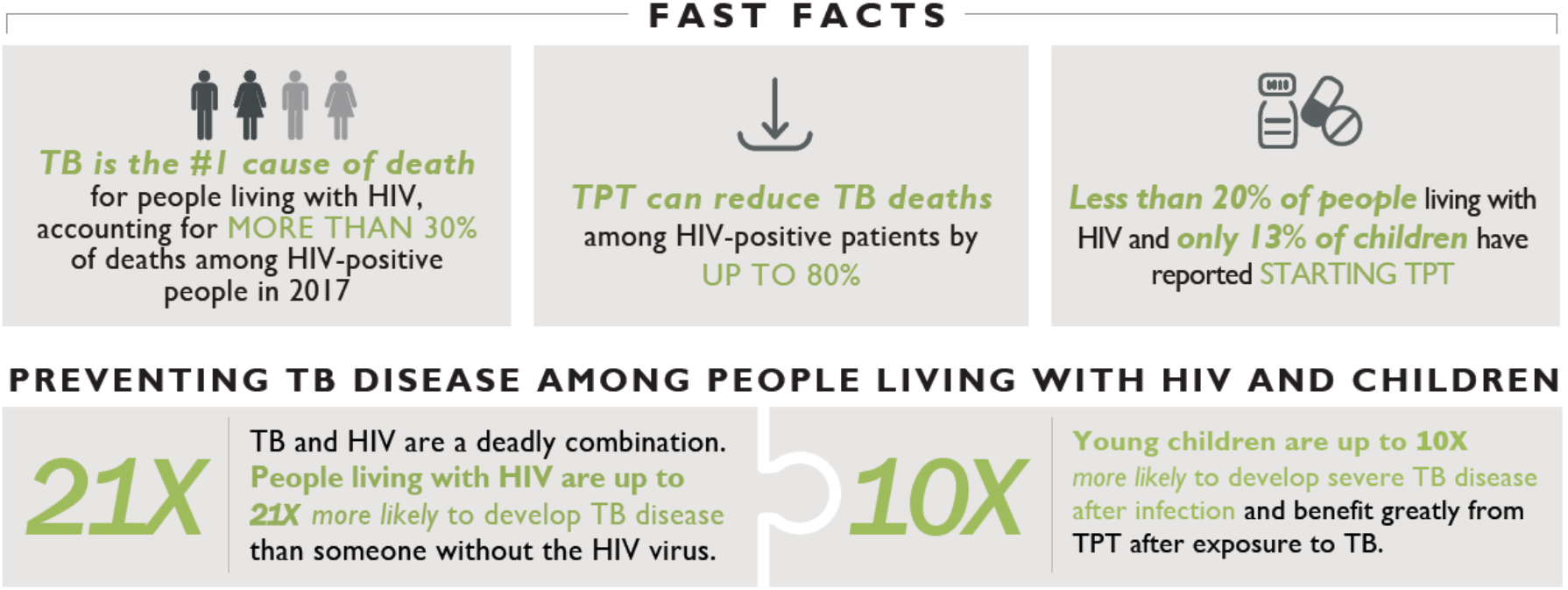
To stay in the loop and for continuous opportunities to learn about how to influence and monitor PEPFAR programs, please email at: info@pepfarwatch.org

Advocacy to ensure the prioritization of TB Preventive Therapy in PEPFAR COPS

Lynette Mabote

23 January 2019

Why Is TB Preventive Therapy (TPT) Important for PEPFAR COPS?

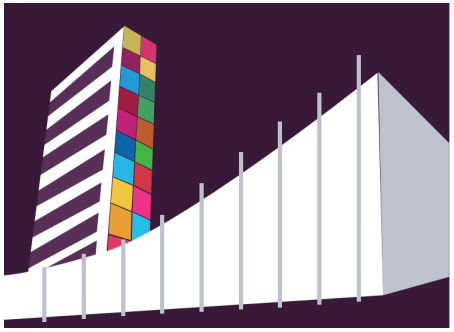


from CDC Division of Global HIV and TB

- We've known for decades that TB preventive therapy reduces the risk that someone with TB infection will fall sick with active TB disease.
- Yet in 2017

  …fewer than 1 million PLHIV were started on TB preventive therapy (most on isoniazid preventive therapy—IPT)

  … only 300,000 of the more than 1.3 million child household contacts <5 years received TPT



WE HAVE AMBITIOUS NEW TB PREVENTION TARGETS

UN High-Level Meeting ON TB Political Declaration

- “Commit to prevent TB for those most at risk of falling ill through the rapid scale-up of access to testing for TB infection, according to the domestic situation, and provision of preventive treatment, with a focus on high-burden countries so that at least 30 million people, including 4 million children under five years of age, 20 million other household contacts of people affected by TB, and 6 million people living with HIV and AIDS, receive preventive treatment by 2022, with the vision to reach millions more…”

We have new TPT regimens
that are shorter and safer than IPT

- The "IPT only" era is over!!!!
- Short course TPT regimens include:

3HP= 12 once-weekly doses of rifapentine (**P**) + Isoniazid (**H**)

3HR = three months of daily rifampicin (**R**) + Isoniazid (**H**)

4R = four months of daily rifampicin (**R**)

IPT — given daily for 6 months (6H), 9 months (9H), or up to 36 months (continuous IPT), or as a fixed-dose combination with cotrimoxazole and vitamin B6 in a product called **Q-TIB**

3HP= 12 once-weekly doses of rifapentine (**P**) + Isoniazid (**H**)

900 mg P | 900 mg H

- Shorter in duration than IPT
- Less liver toxicity than IPT
- Higher completion rates than IPT
- Similar efficacy as IPT in preventing TB

3HP can be used to prevent TB in:

- HIV-negative adults
- Adults with HIV who are taking ARVs with acceptable drug-drug interactions
- Children and adolescents age 2–17
- 3HP has not yet been studied in children under age 2—that trial should start soon
- 3HP is not yet recommended for use in pregnant women, because of insufficient data (but research is underway)
- 3HP has not yet studied in people taking OST (e.g., methadone)

Currently the only quality-assured source of rifapentine in 3HP is manufactured by the pharmaceutical company Sanofi.

WHAT DOES PEPFAR 2019 COPS GUIDANCE SAY ABOUT TPT?

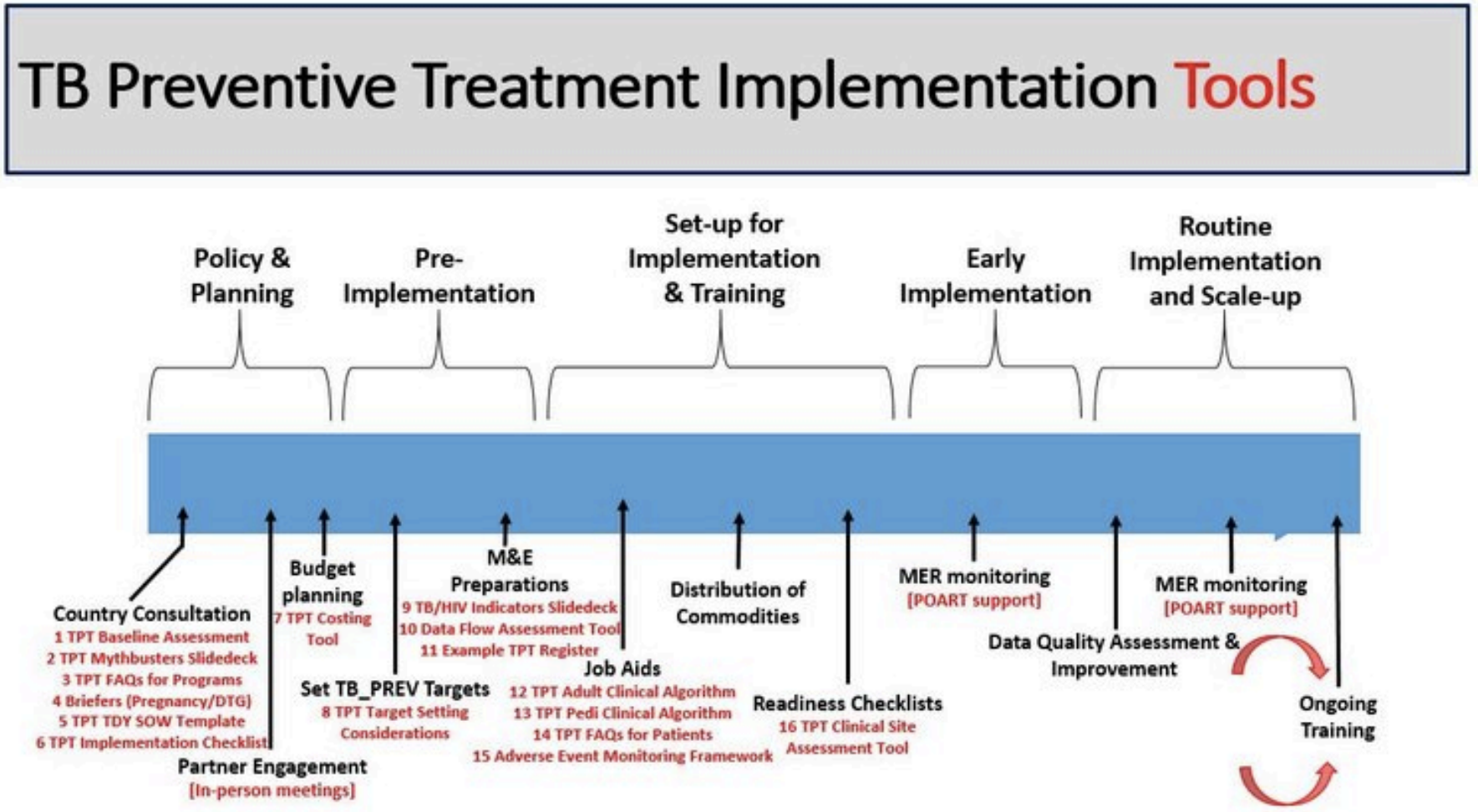
- "In COP19, PEPFAR is renewing focus on TB preventive treatment; TPT for all PLHIV (including pregnant women and children) must be scaled-up as an integral and routine part of the HIV clinical care package. The evidence base for TPT is clear."
- "The use of shorter rifapentine-based regimens (e.g., 3HP) is associated with lower risk for adverse events and higher completion [than IPT]; provided that it become available at a competitive price and pharmacokinetic data demonstrate compatibility with dolutegravir (DTG), it should be the preferred regimen for PEPFAR-supported patients for whom appropriate dosage is available."
- "Countries are expected to fully scale-up TB preventive therapy within adolescents over the next two years, by which time they should have provided TPT to all eligible patients and should be routinely providing it to newly enrolling patients who do not have TB symptoms (or as secondary prevention after TB treatment)."

SO WHAT DO WE NEED TO ADVOCATE FOR DURING PEPFAR COPS?

- The COP19 guidance text on TPT and rifapentine-based TPT is concrete and solid.
- So advocates should put their energy into ensuring that countries follow this guidance and create ambitious TPT scale-up plans.
- There should be well-defined budgets for TPT commodities, including rifapentine.
- We reviewed COP18 Strategic Direction Summaries and found that very few countries mentioned RPT-based TPT. Where TPT was mentioned, countries focused on IPT or INH/cotrimoxazole.
- This needs to change. No country should only be using IPT. Countries need to introduce shorter, safer TPT regimens based on rifapentine.
- These shorter, safer rifapentine-based TPT regimens should be offered to adults, young people, and children >2.
- PEPFAR programs should budget for contact investigations—if someone is diagnosed with TB, offering TPT to their household contacts once active TB is ruled out.

PEPFAR HAS DEVELOPED TPT IMPLEMENTATION TOOLS

www.pepfarsolutions.org



TPT tools have everything from a myth busters slide deck to TPT costing tools to sample clinical algorithms. *These can be tools for advocates and for programs!*

Overcoming Resistance to Implementing 3HP and TPT

- Excuse: Rifapentine is too expensive. We're going to stick with INH only.
- Response: At $15/24-tablet blister pack, the rifapentine component of the 3HP regimen currently costs $45. This is much more expensive than IPT and the price absolutely needs to come down. Lowering the price will require everyone to act:
- All PEPFAR countries should budget to use 3HP for a portion of their overall TPT targets and plan to transition from IPT to 3HP as the price of rifapentine comes down. Volumes need to rise to bring down the price of rifapentine.
- We need generics! The IMPAACT4TB project funded by Unitaid is working to support the entry of generic producers of rifapentine.
- Sanofi needs to reduce the price of rifapentine to a level countries can afford. Sanofi also needs to register RPT in more countries (in the meantime, most countries can access RPT through the Global Drug Facility/GDF).
- Activists should hold Sanofi accountable on price and access.

Overcoming Resistance to Implementing 3HP and TPT

Overcoming Resistance to Implementing 3HP and TPT

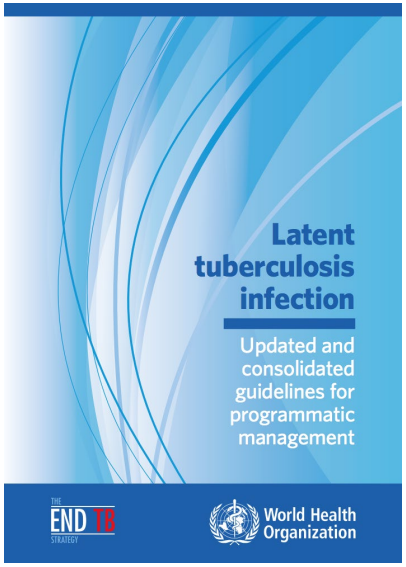
- Excuse: Isn't TPT the TB program's job? Our program is focused on preventing and treating HIV. There's another program for TB.

- Response: We can't end HIV without addressing TB. PEPFAR has said that TPT "must be scaled-up as an integral and routine part of the HIV clinical care package." That means that every PEPFAR-supported program needs to budget for TPT and incorporate TB screening, prevention, and treatment in HIV clinical care. A decision to test for TB is a decision to treat.

- PEPFAR put it this way in COPS guidance: "Countries are now required to report on TB screening of patients on ART, and the two mutually exclusive clinical decisions made from that screening: initiation of TB treatment, or 2) initiation and completion of TPT."

Overcoming Resistance to Implementing 3HP and TPT

- Excuse: There isn't a good test for TB infection or for predicting who with TB infection will progress to active TB disease, so we don't know who to treat with TPT.
- Response: The WHO guidelines on latent TB infection do *not* require a test for infection before starting PLHIV or child household contacts <5 years on TPT. Neither does PEPFAR.



C. Testing for LTBI

- Either a tuberculin skin test (TST) or interferon-gamma release assay (IGRA) can be used to test for LTBI. *(Strong recommendation, very low-quality evidence.* ***New recommendation****)*
- People living with HIV who have a positive test for LTBI benefit more from preventive treatment than those who have a negative LTBI test; LTBI testing can be used, where feasible, to identify such individuals. *(Strong recommendation, high-quality evidence. Existing recommendation)*
- LTBI testing by TST or IGRA is not a requirement for initiating preventive treatment in people living with HIV or child household contacts aged < 5 years. *(Strong recommendation, moderate-quality evidence. Updated recommendation)*

Take home messages

- HIV programs can't afford to ignore TB prevention anymore.
- TPT is a routine part of HIV clinical care in PEPFAR programs.
- We have shorter, safer alternatives to IPT, like the 3HP regimen.
- 3HP is a preferred regimen for PEPFAR, pending a competitive price for rifapentine and confirmation that it's safe to use 3HP with DTG.
- All countries need to set ambitious annual TPT targets.
- Countries should use 3HP to meet a portion of their TPT targets.
- As price comes down, countries should transition from IPT to 3HP to meet annual targets.

LF-LAM, Gene Xpert & Chest X-Ray: Evidence for action and scale-up

Albert S. Makone

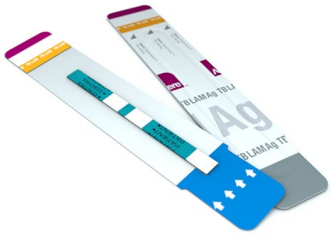
January 2019

Presentation Outline

- Importance of LF LAM assay, Gene Xpert & Chest X-Ray
- How LF LAM fared in 2018 COPs
- 2019 PEPFAR COPs guidance related to TB
- TB relevant sections of the COPs
- Let's Take Action

BENEFITS OF LATERAL FLOW (LF) URINE LIPOARABINOMANNAN (LAM) ASSAY TESTING

- **Saves lives! -** the LAM test is the only TB test shown to reduce deaths. It allows for severely ill people to be started on treatment earlier. (Peter JG, Ziejenah LS, Chanda D, et al, 2016)
- **Aimed at the most vulnerable -** LAM test works best in those sickest with HIV, meaning it targets those most at risk of dying from TB. People with advanced HIV previously lacked other good diagnostic options.
- **Affordable -** LAM test costs just USD 3.50 per test. Unlike other TB tests, LAM requires no special reagents or equipment (only cups for urine collection)
- **Non-invasive -** because the test uses urine, it does not require any uncomfortable procedures as other TB tests can (such as inducing sputum, drawing blood, or taking a biopsy).
- **Simple** - the LAM test is low-tech and requires little training to use. It does not rely on electricity or any special equipment.
- **Fast** - the LAM test provides results in just 25 minutes, making it the fastest TB test.



Source: http://www.who.int/tb/areas-of-work/laboratory/policy_statement_lam_web.pdf
Peter et al. Lancet 2016. http://dx.doi.org/10.1016/S0140-6736(15)01092-2.
Photo from Alere

EVIDENCE FOR URINE LAM TESTING

- A Cochrane Review assessed 12 studies of LAM and found sensitivity of a combination of LF-LAM + sputum Xpert MTB/RIF (either test positive) was 75%, representing a 13% increase over Xpert alone
  Shah et al. http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD011420.pub2/abstract. 2016

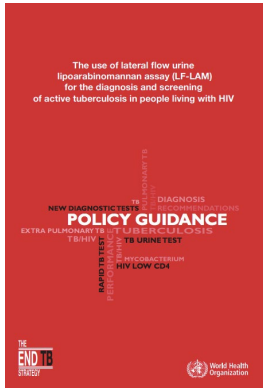
- A randomized clinical trial in **South Africa, Tanzania, Zambia, and Zimbabwe** showed that using LAM was associated with a 4% reduction in the number of people who died in the first eight weeks from any cause. LAM reduced the risk of dying by 17%
  Peter JG, et al. Lancet. 2016. doi: 10.1016/S0140-6736(15)01092-2.

- Urine LAM positivity predicts higher rates of mortality in **South Africa**
  Drain, et al. Clinic-based urinary LAM as a biomarker of clinical disease severity and mortality among ART-naïve HIV-infected adults in South Africa. OFID. 2017.

- Study in **Kenya** shows adding LAM increases diagnostic yield from 47.4% (95% CI: 39.4 to 55.6%) to 84.0% (95% CI: 77.3 to 89.4%) when using clinical signs and X-ray; by 19.9%, from 62.2% (95% CI: 54.1 to 69.8%) to 82.1% (95% CI: 75.1 to 87.7%) when using clinical signs and microscopy; and by 13.4%, from 74.4% (95% CI: 66.8 to 81.0%) to 87.8% (95% CI: 81.6 to 92.5%) when using clinical signs and Xpert.
  Huerga, et al. PLOS ONE. 2017. doi: 10.1371/journal.pone.0170976.

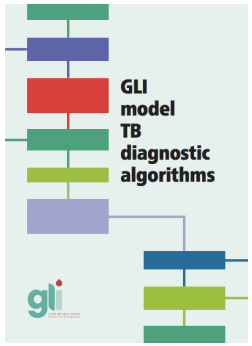
- Routine LAM testing in newly admitted HIV-positive adults in **South Africa** is feasible, provides major improvement in diagnostic yield with high specificity, identifies TB in people without respiratory symptoms and/or unable to produce sputum, and can rapidly identify patients at highest risk of death.
  Lawn S, et al. BMC Med. 2017. doi: 10.1186/s12916-017-0822-8.

EVIDENCE-BASED POLICIES FOR LAM USE



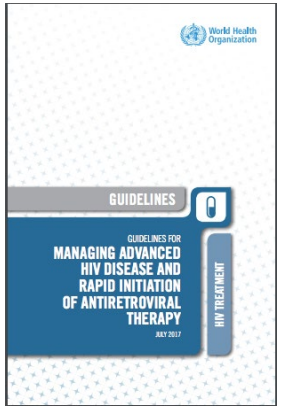
WHO Policy Guidance (2015)

LF-LAM **may be used** to assist in the diagnosis of TB **in HIV positive** adult *in-patients* with signs and symptoms of TB (pulmonary and/or extrapulmonary) who have a CD4 cell count less than or equal to 100 cells/μL, or HIV positive patients who are seriously ill[1,2] regardless of CD4

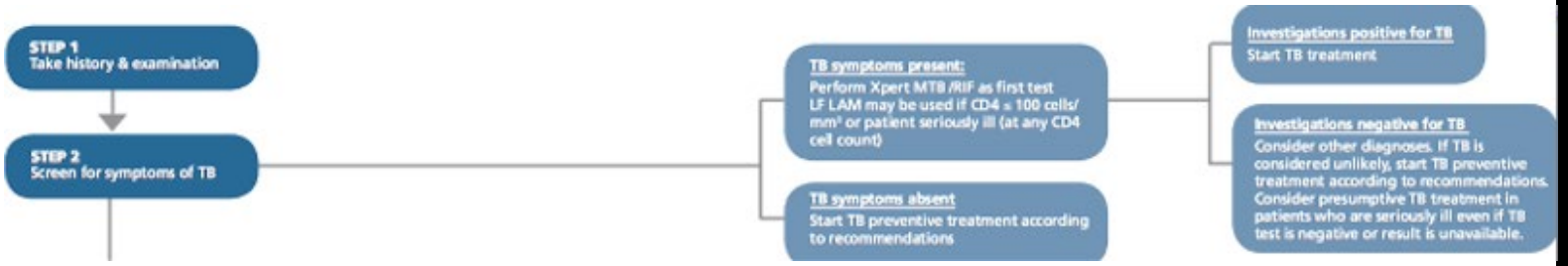


GLI Model TB Diagnostic Algorithms (2017)

The LF-LAM assay may be used to assist in diagnosing active TB in both in-and out-patients who are seriously ill with danger signs, regardless of CD4 count. Testing with the LF-LAM assay may be especially useful for patients unable to produce a sputum specimen. Whenever possible, a positive LF-LAM should be followed up with other tests such as Xpert MTB/RIF. While awaiting results of other tests, clinicians could consider initiating TB treatment immediately based on the positive LF-LAM and their clinical judgment.



WHO Guidelines on Managing Advanced HIV (2017)



LAM AVAILABILITY IN COUNTRIES

- This life-saving test remains vastly underutilized in most high TB/HIV burden countries; only eSwatini, South Africa, and Uganda have scaled up TB LAM testing nationally as at Dec 2018.

COUNTRIES WITH HIGH BURDENS OF TB AND HIV

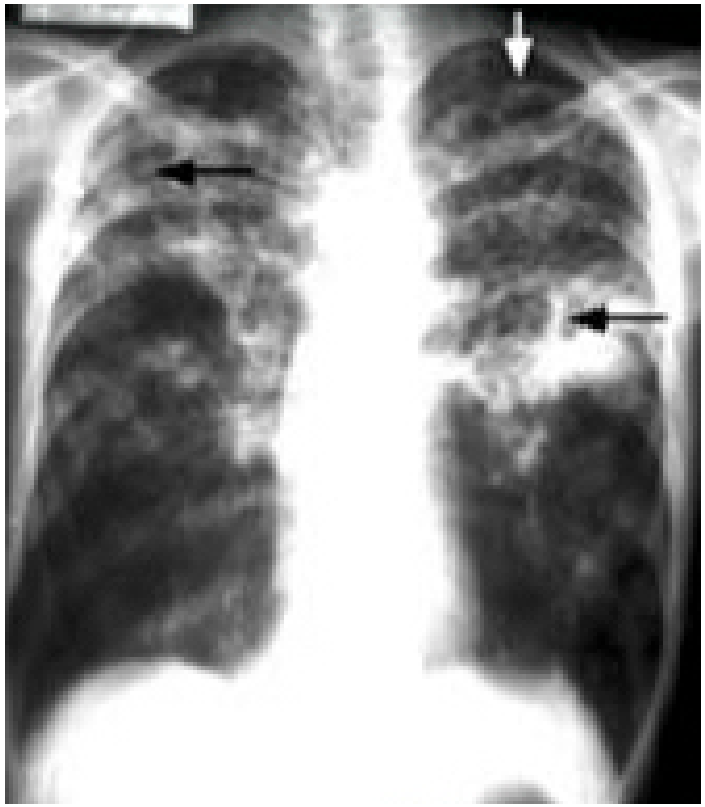
The following countries have high burdens of TB and HIV, and as such should be prioritized for implementation of the LAM test[16]:

Angola	Congo	Lesotho	South Africa
Botswana	DR Congo	Liberia	Swaziland
Brazil	Ethiopia	Malawi	Thailand
Cameroon	Ghana	Mozambique	Uganda
Central African Republic	Guinea-Bissau	Myanmar	UR Tanzania
Chad	India	Namibia	Zambia
China	Indonesia	Nigeria	Zimbabwe
	Kenya	Papua New Guinea	

Image from TAG: http://treatmentactiongroup.org/content/activists-guide-tb-lam-test

CHEST X-RAY

Chest radiography is another option for screening, it can be used together with symptom screening to best determine who should continue on with diagnostic testing



Abnormal Chest X-Ray

Advantages

- Quick
- High sensitivity
- Inexpensive
- Widely used

Disadvantages

- Low specificity
- Requires additional testing
- Cannot be used for extrapulmonary TB
- Active TB doesn't always look the same (especially in people with HIV)

Adapted from Dr. Madhukar Pai

GENEXPERT

GeneXpert system is a cartridge-based test to detect MTB and resistance to the drug rifampicin

- The cartridge is called “Xpert MTB/RIF ULTRA”
  - The new Ultra cartridge is more sensitive than the previous Xpert MTB/RIF cartrdige, especially in people with HIV, people with extrapulmonary TB, and children
- The system analyzes a sample by extracting MTB genetic information, multiplying it, and reading its genetic code
- The WHO recommends GeneXpert as the initial test for all adults and children in need of TB evaluation
- In the future…
  - A cartridge in development may be able to detect resistance to more drugs (isoniazid, fluoroquinolones, and the second-line injectables)

http://apps.who.int/iris/bitstream/10665/254792/1/WHO-HTM-TB-2017.04-eng.pdf

GENEXPERT: ADVANTAGES AND DISADVANTAGES

Advantages:

- One step process—automated
- Quick (results in <2 hrs)
- Requires fewer biosafety measures than culture/LPA, so can be used in lower-level laboratories
- High sensitivity
- High specificity
- Can detect rifampicin resistance
- **Same machine can also be used for HIV, hepatitis C diagnoses/viral load monitoring**
- Can work on many extrapulmonary TB samples

GeneXpert XVI
(Image source: Cepheid)

How LF LAM fared in 2018 COPs

- 2018 COPs were reviewed for the inclusion of TB LAM testing
- Of the 30 COPs analyzed, only 6 countries funded by PEPFAR included TB LAM
- Few countries have included plans for scaling up TB LAM testing
- Countries that included TB LAM in 2018 COPs were:
  - Cote D'Ivoire
  - Malawi
  - eSwatini
  - Kenya
  - DRC
  - Zambia
- 2019 COPs have to be different

2019 PEPFAR COPs guidance related to TB

- Overall framing of the TB LAM test as a life-saving test and important component of care for PLHIV
- Acknowledging delivery of key diagnostic services such as LAM & Gene Xpert are “sub-optimal;” (§ 5.4.3)
- Encouragement that countries go beyond current WHO guidance and provide LAM for people with serious illness or CD4<200 cells/mm^3 (as opposed to CD4<100) (§ 9.8.4)
- Use of clinical criteria to identify patients eligible for an advanced disease care package when CD4 testing is unavailable given PEPFAR’s reduced support for CD4 (§ 9.11.1).

Suggestions for strengthening 2019 COPs

- CSOs should encourage PEPFAR to more strongly emphasize LAM use in outpatient settings, based on available evidence (§ 9.9).
- CSOs should ensure countries do not wait for transitioning to a more sensitive LAM test upon WHO endorsement (§ 9.9)
- Encourage PEPFAR to update the TX_TB indicator from MER 2.3 to include TB LAM testing and chest X-ray as disaggregate indicators under “Diagnostic Test”
- Encourage PEPFAR to include in plans for updating **SIMS** documentation of TB LAM testing (and Xpert) in both in-patient and outpatient facilities.

LETS TAKE ACTION

- No TB diagnostic test is perfect, including the LAM test, but it is an important tool for saving people with advanced HIV from dying of TB.

- PEPFAR can cover purchase of TB LAM & GeneXpert cartridges, sample transport and laboratory network strengthening.

- PEPFAR can cover training and support for National AIDS Program and National TB Program to update their guidance on diagnostic practices, and implement TB LAM and other diagnostics in line with the latest evidence (see slide titled “2019 PEPFAR COPs guidance related to TB”).

- Encourage PEPFAR to develop indicators for TB LAM testing and chest x-ray to measure the implementation of TB LAM and impact on TB diagnosis among PLHIV

For more information

- LAM guide:http://treatmentactiongroup.org/content/activists-guide-tb-lam-test (updated document will be available in February)
- GLI algorithm: http://www.stoptb.org/wg/gli/assets/documents/GLI_algorithms.pdf
- WHO Policy Statement on LF-LAM: http://www.who.int/tb/areas-of-work/laboratory/policy_statement_lam_web.pdf
- WHO Guidelines on managing advanced HIV: http://www.who.int/hiv/pub/guidelines/advanced-HIV-disease/en/
- WHO Policy Updates for GeneXpert: http://apps.who.int/iris/bitstream/handle/10665/112472/9789241506335_eng.pdf;jsessionid=2F40E71E6692826BC754ED1176024575?sequence=1

Acknowledgements

- Treatment Action Group

How to Ensure Pediatric TB is Included in PEPFAR Supported Programs

Webinar:
Good COPs or Bad COPs 2.0
January 23rd 2019

Martina Casenghi, PhD
Technical Director CaP TB Project, EGPAF Switzerland
mcasenghi@pedaids.org

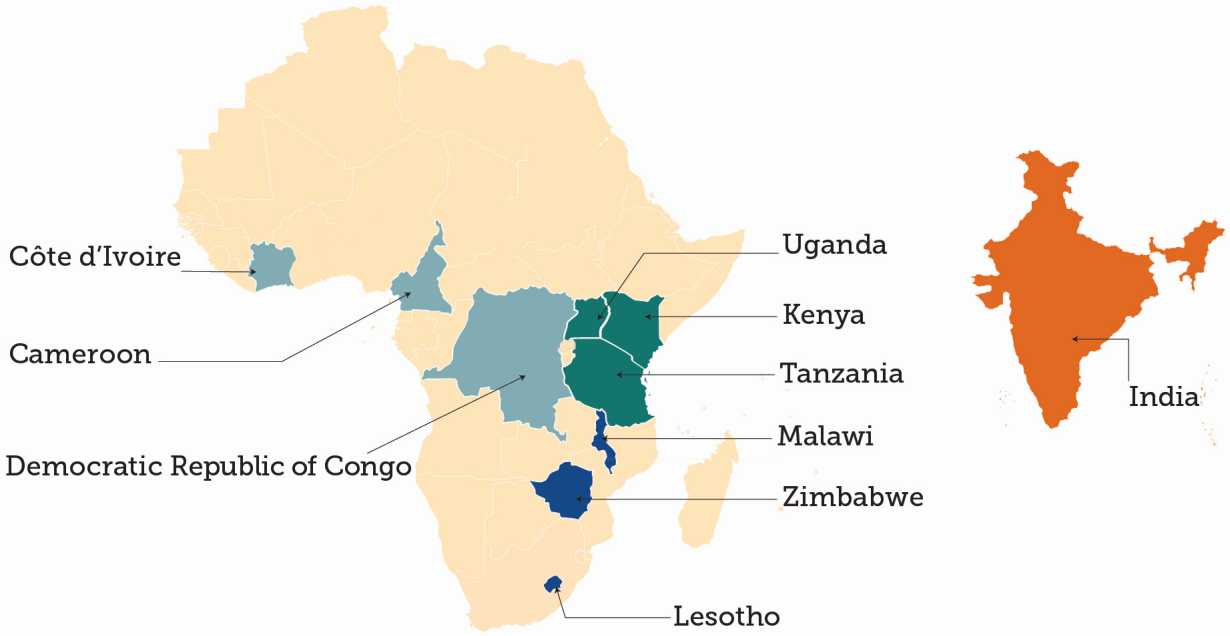
EGPAF - Catalyzing Pediatric TB Innovations

Funder	Unitaid
Lead Grantee	Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)
Budget	36 million USD
Time Frame	2017 – 2021
Objective	To reduce pediatric TB morbidity and mortality in nine Sub-Saharan African countries and India by increasing access to diagnosis and treatment of children with active TB, and increasing access to preventive treatment among eligible children. EGPAF work hand in hand with CSOs to work towards this goal.

Resources hyperlinked

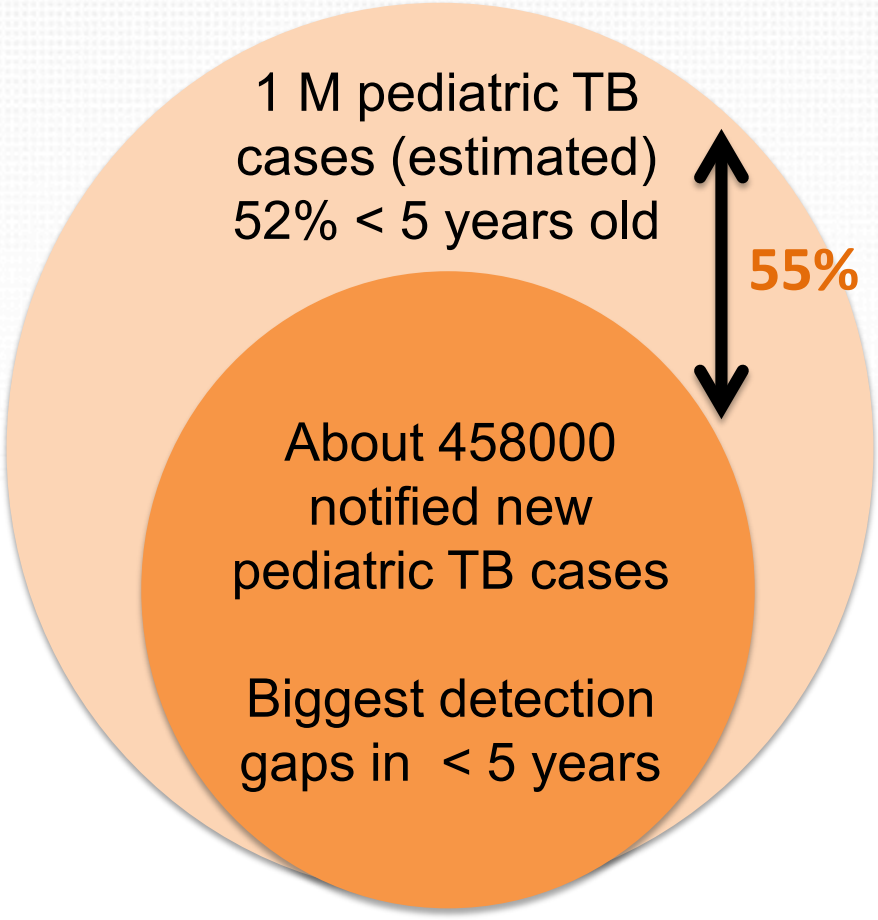
Global Project Fact Sheet (E/F)

Country Project Fact Sheets available here



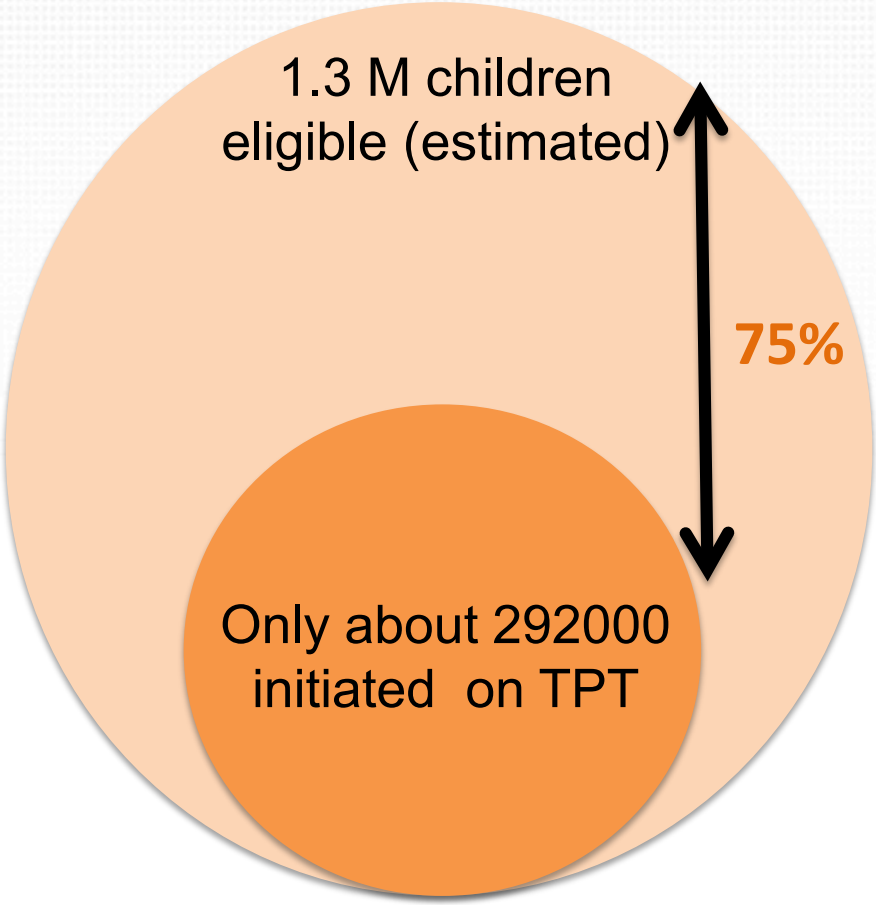
Global Pediatric TB Burden and key gaps

Pediatric active TB disease (2017)



UNHLM Targets by 2022:
TREAT 3.5 M children

Pediatric TB preventive Treatment



UNHLM Targets by 2022:
PROVIDE TPT TO 4 M children <5

Global Tuberculosis Report, WHO, 2018

Pediatric TB: the Silent Epidemic

Pediatric TB has been historically neglected by public health approaches

- Mostly smear-negative TB, thus less contagious
- More difficult to diagnose due to inability to produce sputum and low bacterial load in samples
- No age disaggregated reporting requested from National TB Programs untill recently
- Poor integration of pediatric TB care in entry points where kids access care (i.e HIV, MCH)

Pediatric TB historically embedded in overall TB interventions

- No description of pediatric TB specific interventions such as:
    - Sample collection procedures
    - Pediatric TB-adapted tools for TB screening and for clinical radiological diagnosis
    - Pediatric TB-adapted case findings interventions

- **No earmarked budgets!**

Country preparedness for pediatric TB: EGPAF Survey

PHOTO: ERIC BOND/EGPAF, 2018

Elizabeth Glaser Pediatric AIDS Foundation / Unitaid Innovation in Global Health

NATIONAL POLICY ASSESSMENT:

Creating an Enabling Environment for Effective and Innovative Pediatric Tuberculosis Diagnostic and Treatment Interventions

As part of its Unitaid-supported Catalyzing Pediatric Tuberculosis (CaP TB) project, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) carried out an assessment of the national policy landscape for childhood tuberculosis (TB) in 10 countries (Cameroon, Côte d'Ivoire, Democratic Republic of Congo, India, Kenya, Lesotho, Malawi, Tanzania, Uganda, and Zimbabwe). Information was collected from National TB programs, and confirmed with them, including information until May 30, 2018.

This policy assessment will be used to promote the strongest possible policy, regulatory, and financial environment for introducing and scaling up effective and innovative pediatric TB diagnostic and treatment interventions. The policy indicators closely follow the key actions of the *The Roadmap towards ending TB in children and adolescents*[1], a new global advocacy document launched September 2018 by the World Health Organization (WHO) and several other global health actors, including EGPAF. Below is a brief description of findings from the policy landscape matched against a selection of the *Roadmap's* key actions, together with recommendations on how to meet the *Roadmap's* "Implementation Milestones".

Strengthen advocacy at all levels

Related Policy Indicator	Policy assessment result
Country had a TB public outreach campaign.	Half of the countries had at least one public event on childhood TB in 2018. However, a single event is no substitute for an outreach campaign.
CALL TO ACTION: Countries need to ensure high public awareness of the childhood TB epidemic. Public outreach campaigns improve general awareness of key issues related to pediatric TB and can foster advocacy by affected communities for better access to TB prevention and treatment. It is important to involve families affected by TB in related campaigns at the community level. Links to the *Roadmap's* Key Action 1 "Strengthen advocacy at all levels" and Key Action 3 "Foster functional partnerships for change".	

Foster national leadership and accountability

Related Policy Indicator	Policy assessment result
Childhood TB is included in the National TB Strategic Plan (NSP) with priority intervention areas specified.	All countries have a NSP, which included childhood TB, but just six of 10 specifically include all, or almost all, key intervention areas.
An active Pediatric TB National Working Group (PTNWG) is operational.	Six of 10 countries have an active Pediatric TB National Working Group, and two additional countries have a dedicated pediatric work stream in the general TB working group.
There is a National TB Program (NTP) focal person for childhood TB.	All countries, except one, have a focal person.
CALL TO ACTION: Countries need to prioritize all key childhood TB interventions in national plans, supported by adequate governmental structures such as PTNWGs and focal points. It is promising that childhood TB is included in NSPs and that the majority of countries have either an active PTNWG or focal point. However, specifics in NSPs are lacking, and most do not cover all the priority pediatric TB interventions. Links to the *Roadmap's* Key Action 2 "Foster national leadership and accountability" and Key Action 7 "Scale-up child and adolescent TB case-finding and treatment".	

[1] The key action icons in this policy assessment are shared through the Creative Commons Attribution, from the *Roadmap towards ending TB in children and adolescents*. Geneva: World Health Organization; 2018-09-26 http://apps.who.int/iris/bitstream/handle/10665/274374/9789241514668-eng.pdf?ua=1

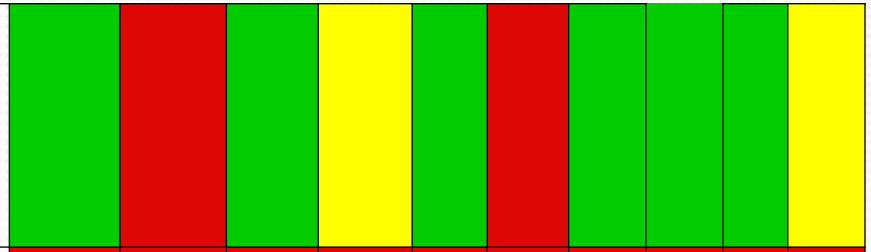
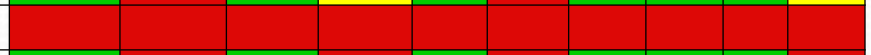
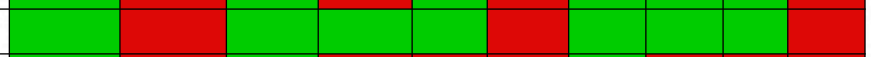
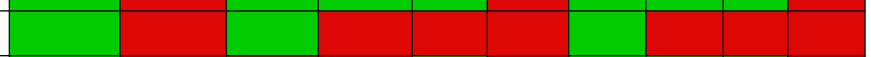
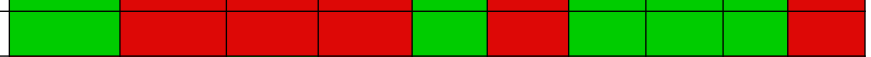
Questionnaire built to assess country preparedness for Childhood TB Programming

- Political will/high level commitments
- Inclusion of pediatric TB related activities in NSP budgets and GF funding requests
  - Technical "preparedness", i.e.:
    - updated guidelines
    - availability of TBWGs
    - availability of SOPs

Source: EGPAF, analysis across project 10 countries, May 2018

Link to the Policy Assessment document: http://tiny.cc/pediatricTBPolicyBrief

EGPAF Survey on Countries' Preparedness for Childhood TB: the Example of GF Funding Requests

The GF funding request (2017-2019) includes activities for childhood TB		
If yes to 1.6, please indicate if specific activities are included for (tick all that apply):	BCG vaccination	
	Active case finding for the pediatric population (*i.e.* contact investigation)	
	Diagnosis of pediatric TB	
	Treatment of pediatric DS-TB	
	Treatment of pediatric MDR-TB	
	Treatment of LTBI in the pediatric population	
	Monitoring and evaluation	
	Other, please specify (*i.e.* integration into other health services)	

- Childhood TB included in GF request 2017-2019 in 6/10 countries
- In 4 countries Childhood TB was not adequatley included (in 2/4 countries Childhood TB has been included but no specific activities have been detailed)

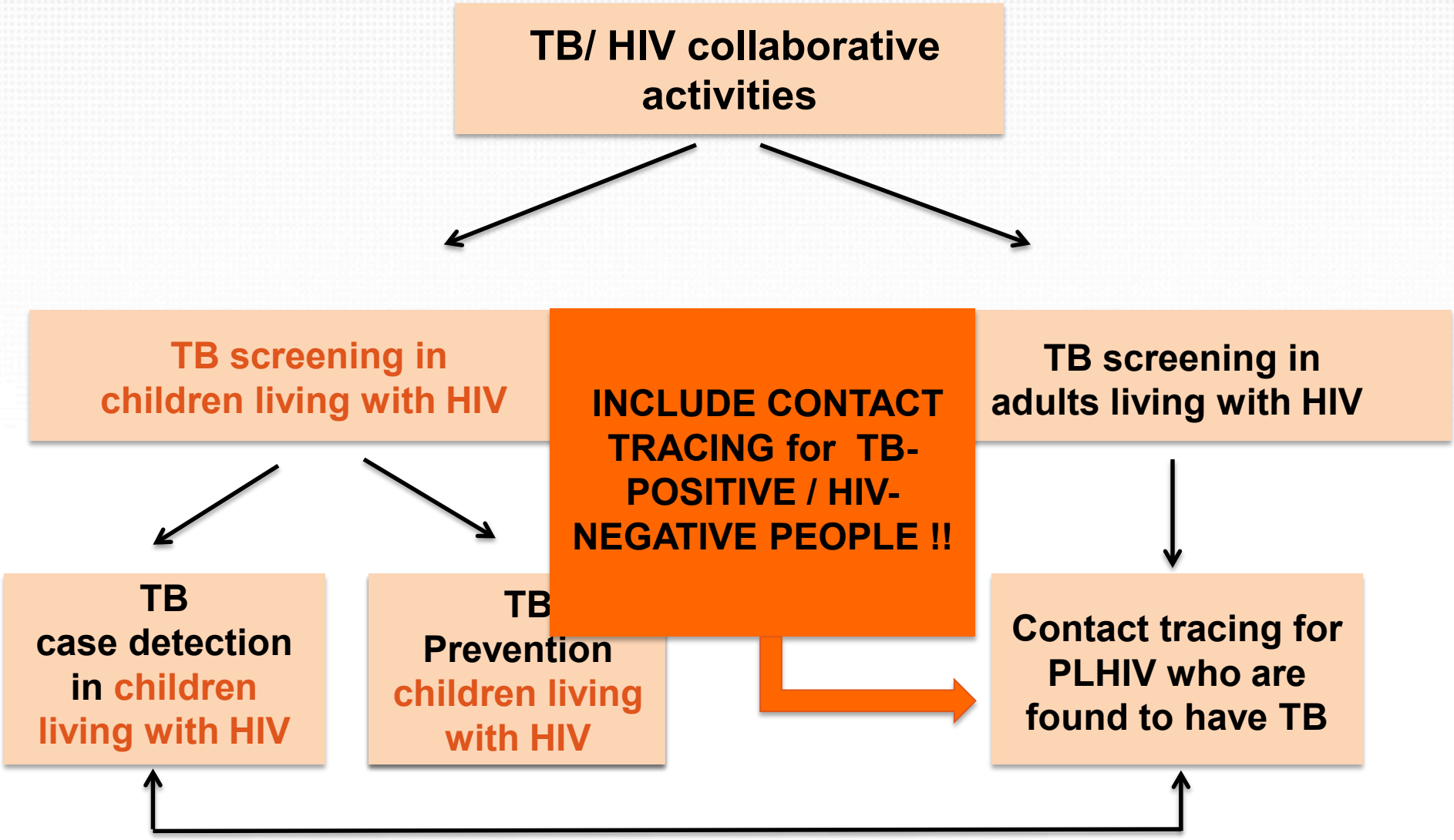
Prioritizing Pediatric TB on Donors' and on Countries' agendas

- GF funding requests are just one of the examples illustrating how we have been failing in adequately addressing pediatric TB
- Lack of specificities on the pediatric TB interventions in national strategic plans and on funding requests hinders scale-up of pediatric TB programming
- Evolving landscape: more and more countries will be requested to increase co-funding from domestic sources
- TB (and pediatric TB) allocations from domestic funding and other donors/sources will have to play an increasing critical role
- **PEPFAR COP 2018: TAG analysis shows same trend: poor inclusion of pediatric TB interventions**

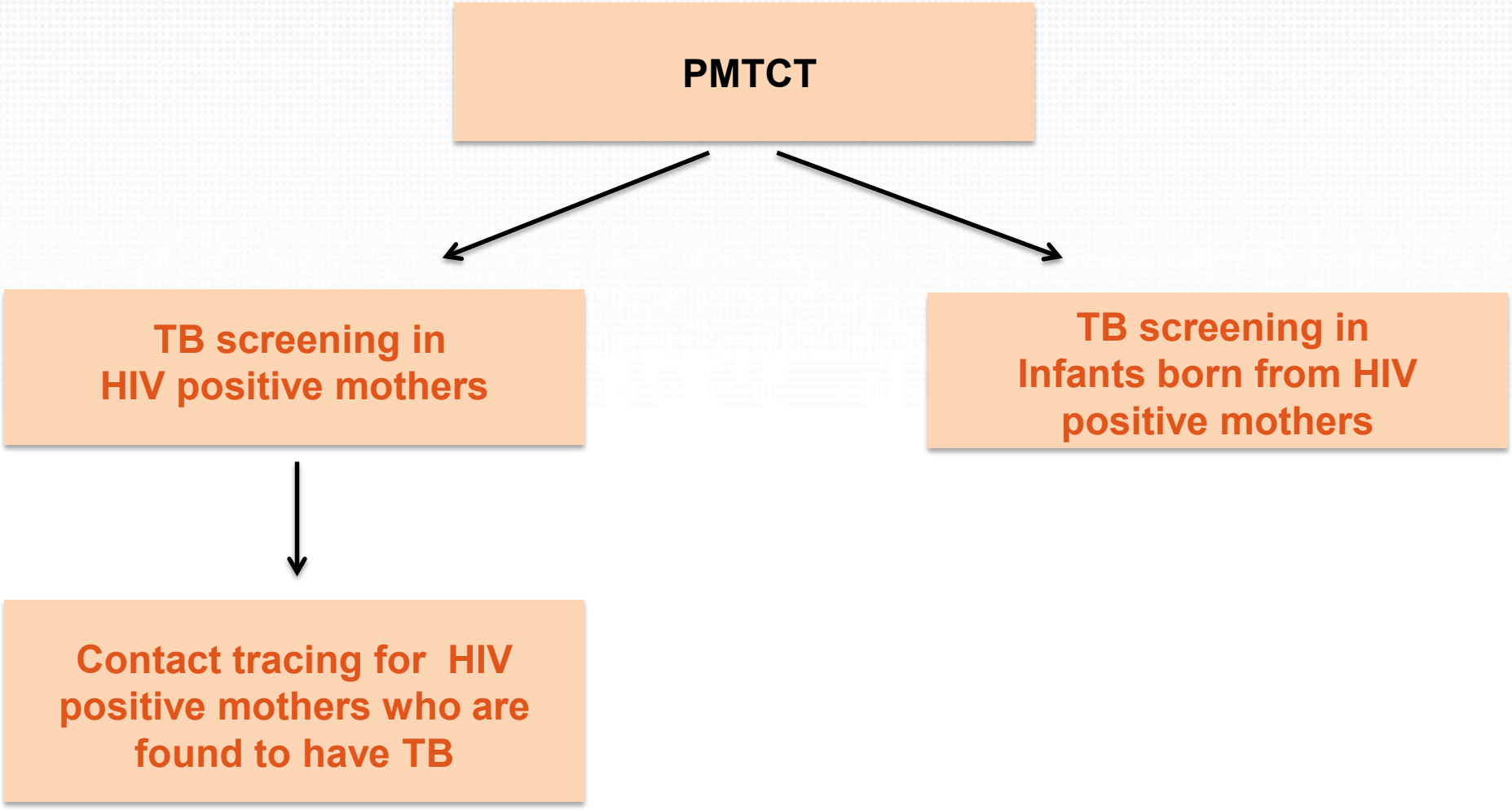
PEPFAR COPs and Pediatric TB: Important Areas of Focus

- Strategic interventions (and related practical implications for implementation)
- Synergistic approaches
- Targets
- Budget elements

PEPFAR COPs and Pediatric TB: Strategic Interventions to Focus on



PEPFAR COPs and Pediatric TB: Strategic Areas to Focus on



PEPFAR COPs and Pediatric TB: Intervention and Practical Implications to Include

TB screening in children living with HIV

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Use of **child adapted TB symptom-based screening tool**

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Training material and job aids to include child- adapted symptom based screening (4 symptoms screening plus specifics signs and symptoms for childhood TB)

PEPFAR COPs and Pediatric TB: Interventions and Practical Implications

TB case detection
in children living with HIV

DIAGNOSIS:

- Ultra as the initial diagnostic test for diagnosis of TB in children
- Implementation of sample collection procedures (Gastric Aspirates, Nasopharyngeal aspirates etc.)
- Integrated sample transportation network (frequency to be adapted in order to meet requirements for TB samples!!)
- Building of HCWs capacity for clinical-radiological diagnosis of pediatric TB (training material and training programs)
- Digital CXR

PEPFAR COPs and Pediatric TB: Interventions and Practical Implications

Treatment of active TB
in children living with HIV

TREATMENT:

- include procurement of Pediatric TB dispersible FDCs (RHZ 75/50/150 and RH 75/50)
- Include procurement of **Ethambutol dispersible single formulation** (COP budget to support procurement)

IMPORTANT: inclusion of EMB in the treatment regimen is recommended in all HIV high-burden countries

PEPFAR COPs and Pediatric TB: TB preventive therapy

TB case prevention
in children living with HIV

↓

TEST OF INFECTION:

- TST or IGRA testing is **NOT** required -MAKE SURE THIS IS MANTAINED
- NEGATIVE SYMPTOM-BASED SCREENING IS SUFFICIENT to exclude active TB

TREATMENT:

- PEPFAR guidance recognizes the need for special considerations for TPT in children
- Consider 3 RH regimen (shorter regimen with RH 75/50 dispersible formulation) for children on Efavirenz
- 6 INH for children on nevirapine, lopinavir-ritonavir, darultegravir
  (COP budget to support procurement of **child-friendly dispersible formulation**)

PEPFAR COPs and Pediatric TB: Synergistic Approaches

TB CONTACT TRACING and ADHERENCE SUPPORT ACTIVITIES:

Ensure that PEPFAR-Supported Lay Cadre Position Descriptions includes following activities:

- Delivery of facility based symptom-based TB screening
- House-hold contact investigation for TB index cases (also for TB positive/HIV negative patients)
- TB treatment adherence support

Example:

Cadre Type	Location	Activities
Linkage & Adherence Support Cadre Titles: - Linkage Facilitators - Community Linkage Facilitators - Patient Tracers	Facility and Community	• Recruitment and bi-directional referral of priority populations (including peer tracing for peer facilitators) • Adherence support • Index testing referral • **TB contact investigation** • **TB adherence support**

PEPFAR COPs and Pediatric TB: TB/HIV Indicators and Targets Disaggregated by Age

- **Indicators and Targets to be disaggregated by age**
- **Age bands 0-4 years; 5-14 years; > 15 years**

Examples:

- Number of ART patients who were screened for TB at least once during the reporting period
- Number of ART patients who were positive by TB symptom based screening
- Number of ART patients who had a specimen sent for bacteriological diagnosis of active TB disease
- Number of registered new and relapsed TB cases (with and without documented HIV status during the reporting period

PEPFAR COPs and Pediatric TB: Budgeting Elements

TRAININGS:

Pediatric TB specific Training material and job aids for Lay cadre/Community Health care workers and for Clinicians/ Health Care workers

INFRASTRUCTURE UPGRADES:

Infrastructure upgrades to make facilities compliant **with Infection Control** measures **for sample collection procedures**

SAMPLE TRANSPORTATION:

- Integrated sample transportation network (TB and HIV samples)
- **Frequency of pick-ups to meet TB samples transportation requirements (budget available for ad-hoc pick-ups or pick up 3 times a week)**

PROCUREMENT:

- **Pediatric TB drugs**: INH and EMB dispersible single formulation
- **Consumables and devices for sample collection procedures**
- **Digital CXR**

PEPFAR COPs and Pediatric TB: CONCLUSIONS

- PEPFAR COP 2019 Strategic Guidance offers important opportunities to strengthen pediatric TB care and to help filling some key gaps - **next 6 weeks will be critical**

- Critical to ensure that **children are specifically mentioned as a target** population for TB/HIV collaborative activities

- Critical to ensure that all elements that are **specific** to delivery of adequate pediatric TB care are included in the interventions otherwise access to care will be suboptimal:
  - Sample collection procedures (and related infection control requirements)
  - Training of HCWs on clinical diagnosis for pediatric TB
  - Availability of pediatric TB formulations

- Critical to make sure that key elements of pediatric TB interventions are **adequately planned for and budgeted**

- **Numbers are needed** to get pediatric TB out of the dark: important to have age disaggregation (0-4 years; 5-14 yewars and > 15 years) for all key indicators

Thank you!

CaP TB project was made possible thanks to the funding and support of Unitaid.
Unitaid accelerates access to innovation so that critical health products can reach the people who most need them.

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Thank you!

Questions?

TAG
Treatment Action Group