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**SCALING UP TB PREVENTIVE  
THERAPY ADVOCACY  
IN PEPFAR 2020COPS**

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# LATENT TB INFECTION (LTBI)



Latent tuberculosis infection

Updated and consolidated guidelines for programmatic management

THE END TB STRATEGY



World Health Organization

*“Latent tuberculosis infection (LTBI) is defined as a state of **persistent immune response to stimulation by Mycobacterium tuberculosis antigens** with no evidence of clinically manifest active TB.”*

*“TB can lie dormant for decades before it strikes; **almost a quarter of the globe** – or 1.7 billion people – is affected by latent TB infection. People with latent TB infection have no symptoms, are not contagious and most of them don’t know they’re infected.”*

[impaact4tb.org](http://impaact4tb.org)

# OUR TB PREVENTION STRATEGIES

1

Give people TB preventive therapy (TPT)

2

Practice good infection control (IC) - **\*Opening the windows\***

- In health centers and clinics
- In communities, families, and homes

3

Find and treat active TB disease (active case finding)

4

Vaccinate against TB administered to babies and young children  
**[the only vaccine against TB is Bacille Calmette-Guerin (BCG)]**

5

For PLHIV, treat HIV with ART ( **Unfortunately, ART enough to prevent TB in PLHIV**)

# WHY THE BUZZ ABOUT TPT?

- **TB** remains the **# ONE cause of death** among people living with HIV (> 30% HIV-positive deaths in 2017)
- **People living with HIV** are up to **21X** more likely to develop TB than those who are HIV-negative.
- Young **children** are up to **10X** more likely to develop TB (esp. household contacts, est. 1.3 mill bacteriologically confirmed TB cases).

- TPT can **reduce deaths among HIV-positive by up to 80%**

*from CDC Division of Global HIV and TB*

- **WHO 2018 TB REPORT: 65 countries** reported initiating TPT for **1.8 million PLHIV**
  - Substantially higher than the 30 000 people in 2005

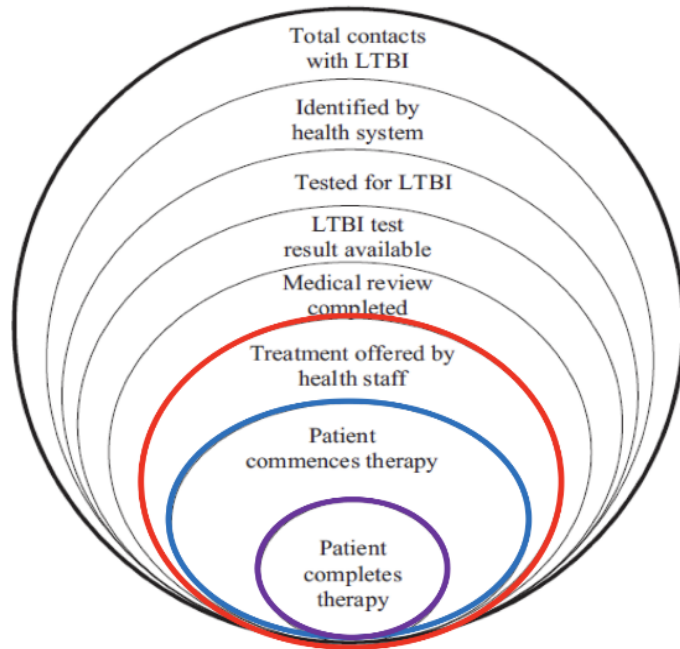
# WHAT IS OUR TPT TARGET (GOAL) FOR 2022?

The HLM 2018 TB Political Declaration commits to providing TPT to at least **30 million people** by the year **2022**. Disaggregated into;

- **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

# THE ISONIAZID PREVENTIVE THERAPY (IPT) DILEMMA

Not prescribed, not taken



Completion rates varied from 6% to 94%

**“... and were inversely proportional to the duration of treatment”**

Fox et al 2017 IJID

WHO 2018 Guidelines on the management of latent tuberculosis infection

4

**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

# WE HAVE NEW TPT REGIMENS SHORTER & SAFER THAN IPT

Short course TPT regimens include:

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

**1HP** = 4-week daily dose of rifapentine (**P**) + Isoniazid (**H**) \*  
[only been studied in PLHIV]

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

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

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**The “IPT only” era is over!!!!**

**3HP** = 12 once-weekly doses of rifapentine (**P**) + Isoniazid (**H**)  
900 mg P | 900 mg H

***Shorter duration*** than IPT ( 3 vs 9-36 months)

***Less liver toxicity*** than IPT

***Higher completion rates*** than IPT

Similar efficacy as IPT in preventing TB



**3HP** = 12 once-weekly doses of rifapentine (**P**) + Isoniazid (**H**)  
900 mg P | 900 mg H

## Prevents TB in

- **HIV-negative** adults
- **Adults with HIV taking ARVs** with acceptable drug-drug interactions (i.e. *dolutegravir, efavirenz*)
- **Children and adolescents** age 2–17 (*\* Trials under way for studying 3HP in children under age 2*)
- 3HP is **not yet recommended for use in pregnant women** - insufficient data (*research results to be released in 2020*)
- 3HP has **not yet studied in people taking OST** (e.g., methadone)

# PEPFAR COP GUIDANCE PUSHES FOR TPT

## Here is what the 2020 PEPFAR COP Guidance says:

- “Scale-up of TPT for all PLHIV and eligible household contacts of PLHIV with TB disease needs to be an integral part of the clinical care package.”
- “PEPFAR has committed to fully scaling-up TPT over COP19 and COP20, and targets have been set accordingly; therefore, all PEPFAR-supported care and treatment programs should be fully engaged in aggressive TPT scale-up with clear timelines to 100% achievement.”
- “Sanofi announced limited availability of rifapentine at a competitive price of ~\$15 per course, however sufficient production is still pending. If and when there is sufficient production, rifapentine-based regimens (e.g., 3HP) will be the preferred PEPFAR regimen for TPT for adults and adolescents. PEPFAR OU teams are encouraged to support the Ministries of Health in their plans to scale-up 3HP.”

# INCREASED ALLOCATIONS IN PEPFAR PLANNING LETTERS

## COP 2019 Technical Priorities

### Tuberculosis

PEPFAR OUs are expected to offer Tuberculosis Preventive Treatment (TPT) as a routine part of HIV care, which means that all care and treatment partners are expected to offer TPT and report on it. Programs are expected to fully scale TPT over the next two years, such that all PLHIV who are on treatment and are eligible for TPT have received a course by the end of COP 2020. Therefore, the TB\_PREV targets included in this letter were set as described above under the target table. For COP 2019, the number of patients that are expected to complete a course of TPT in OU is 585,411, approximately half the total number of eligible PLHIV, per the mandate from S/GAC to fully scale TPT over the next two years. COP 2020 TB\_PREV targets will cover the remaining 50% of the eligible PLHIV on ART, adjusted upward for those that will be newly enrolled in ART during the COP 2019 implementation period. In order to ensure successful programming, it is expected that, at a minimum, \$3,278,301 will be budgeted for TPT commodities.

# WHAT WE LEARNT FROM 2019 COP PROCESS?

## WE WERE ROOKIES!!!

- Lack of preparation by most stakeholders (incl. clear CSO/ community 'voice')
- PEPFAR country reps were still pushing for IPT in COP documents & budgetary allocations ———> fiscal concerns rather than programmatic effectiveness
- No push for **LTBI Policy Reform** at domestic level by CSOs
- Creativity missing in how TPT could be incorporated into other programmes (such as the DTG package or DSD models)

## RESULT:

- Funds allocated to dysfunctional IPT programmes
- Weak outcomes for incremental introduction of newer TPT regimens (i.e. 3HP, 1HP, 3HR, 4R)

# HOW DO WE DO BETTER IN THE 2020 COP PROCESS?

- **Focus** on *2020 Planning Letter*. Look out for TPT language, including *targeted numbers* of people to initiate on TPT and *financial allocations*
- **Review** existing quarter trend data from Amfar's PEPFAR Monitoring website: [www.mer.amfAR.org](http://www.mer.amfAR.org)
- **Set targets** (aligned with your community-based priorities) to include the number of people living with HIV (incl. children) who should be on the newer TPT regimens (i.e. 3HP)
- **Develop language** (using existing data & Planning Letter) to justify your 'target selection' in the *People's COP*

**US\$15/patient-course** for the Sanofi product for eligible countries (a 60% price discount).

**Macleods FDC product MIGHT also be around \$15/patient-course.**

# PUSHING TPT INTO DIFFERENTIATED SERVICE DELIVERY MODELS (DSD)

*Instruction from COP Guidance:* (refer to page 287)

“DSD models for **stable PLHIV** should include **all recommended TB/HIV services** provided to PLHIV, including **regular TB screening and TB preventive treatment (TPT)**”

“**TPT to be delivered to all PLHIV** as part of a **comprehensive package of HIV care**, certain programmatic **adaptations must be considered to ensure PLHIV already in these differentiated service delivery models complete a course of TPT.**”

“...for PLHIV newly initiating ART ...encouraging **completion of TPT (3HP or 5-6 months of INH)** before enrolling otherwise eligible PLHIV in a differentiated service delivery model.”

# OVERCOMING PRICE RESISTANCE TO IMPLEMENTING 3HP

## Excuse:

Rifapentine is too expensive. We're going to stick with INH only.

## Response:

- The price has been reduced. **All PEPFAR countries** should budget to use 3HP for a *[portion of their overall]* TPT targets and plan to transition from IPT to 3HP. ***Volumes need to rise to bring the price of rifapentine down!***
- **Market entry of generics!** MacLeods introducing a new 3HP FDC
- **Sanofi** now has discounted offer on 3HP
- **Sanofi** and **MacLeods** will continue to register TPT in more countries

# TAKE HOME MESSAGES

- PEPFAR is pushing for TPT in all their programs. This should be an essential part of all TB and HIV programs
- All countries should be scaling-up use of short-course, rifapentine-based TPT regimens (3HP, 1HP)
- Rifapentine is now AFFORDABLE. We expect the generic 3HP FDC from Macleods to come in soon (*\*we know price can come down even further, but only at higher volumes\**)
- TPT is NOT a standalone activity. We should ask integrated service delivery through PEPFAR programs (i.e. integrated 3HP/ 1HP into the DTG package & DSD models, into ARV treatment start for newly diagnosed individuals, etc.)

**No one wants to go through the trauma of undergoing treatment for TB. #Prevent2Protect with 3HP**



LE GUIDE DU COMMUNAUTAIRE POUR LA  
**RIFAPENTINE**  
COMME TRAITEMENT DE LA TBCC INFÉCTION

# THANK YOU



AN ACTIVIST'S GUIDE TO  
**RIFAPENTINE**  
FOR THE TREATMENT OF TB INFECTION

Kindly refer to TAG's Rifapentine  
Activists Guide for more  
information on the what, where,  
how and why on 3HP. **Available in  
English, Portuguese, Kmher &  
French**