

#TBIntheTimeofCOVID-19

#PreventionIsPowerful

TB PREVENTIVE THERAPY ADVOCACY

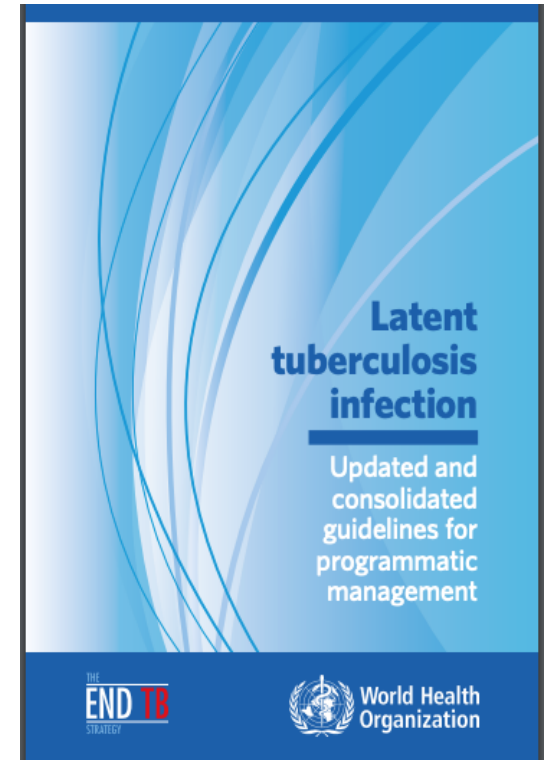
PEPFAR COP/ROP21

#TPTSAVESLIVES

**TREATMENT ACTION GROUP
21 JANUARY 2021**

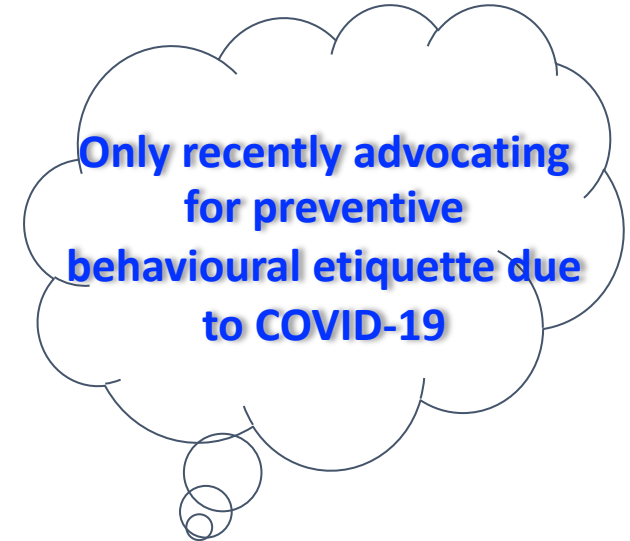
BASICS: TB INFECTION

- “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.
- **5–10%** of those who are infected will develop active TB disease over their lifetime.
- The risk for active TB disease after infection depends on several factors, the most important being immunological status.
- People living with HIV are up to **21X** more at risk of developing TB, young children & adolescents are up to **10X** more likely to develop TB)



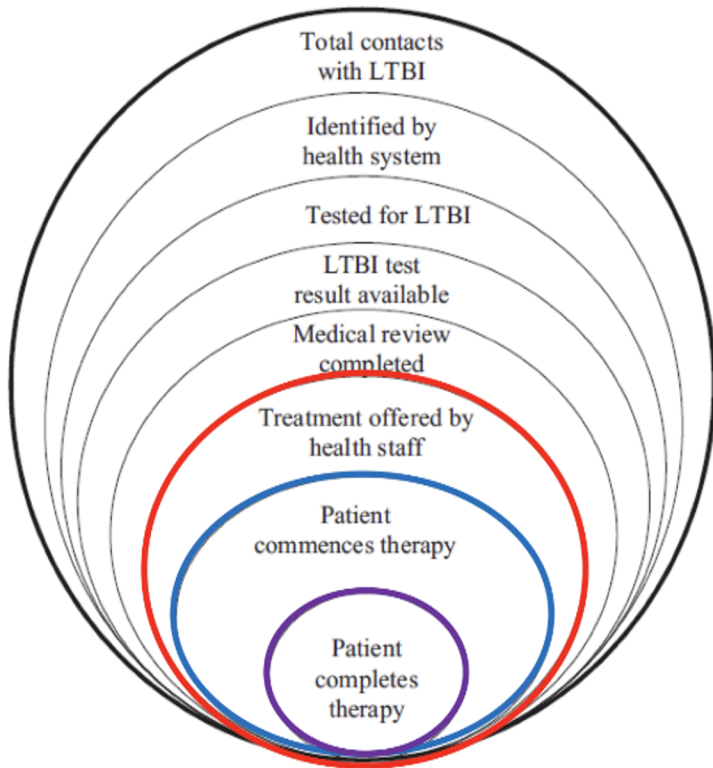
TB PREVENTIVE MEASURES/ MESSAGES TO DATE

- 1 Give people TB preventive therapy (TPT)/ IPT
- 2 Practice good infection control (IC)
 - 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, treating HIV with ART (unfortunately, ART is NOT enough to prevent TB)



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

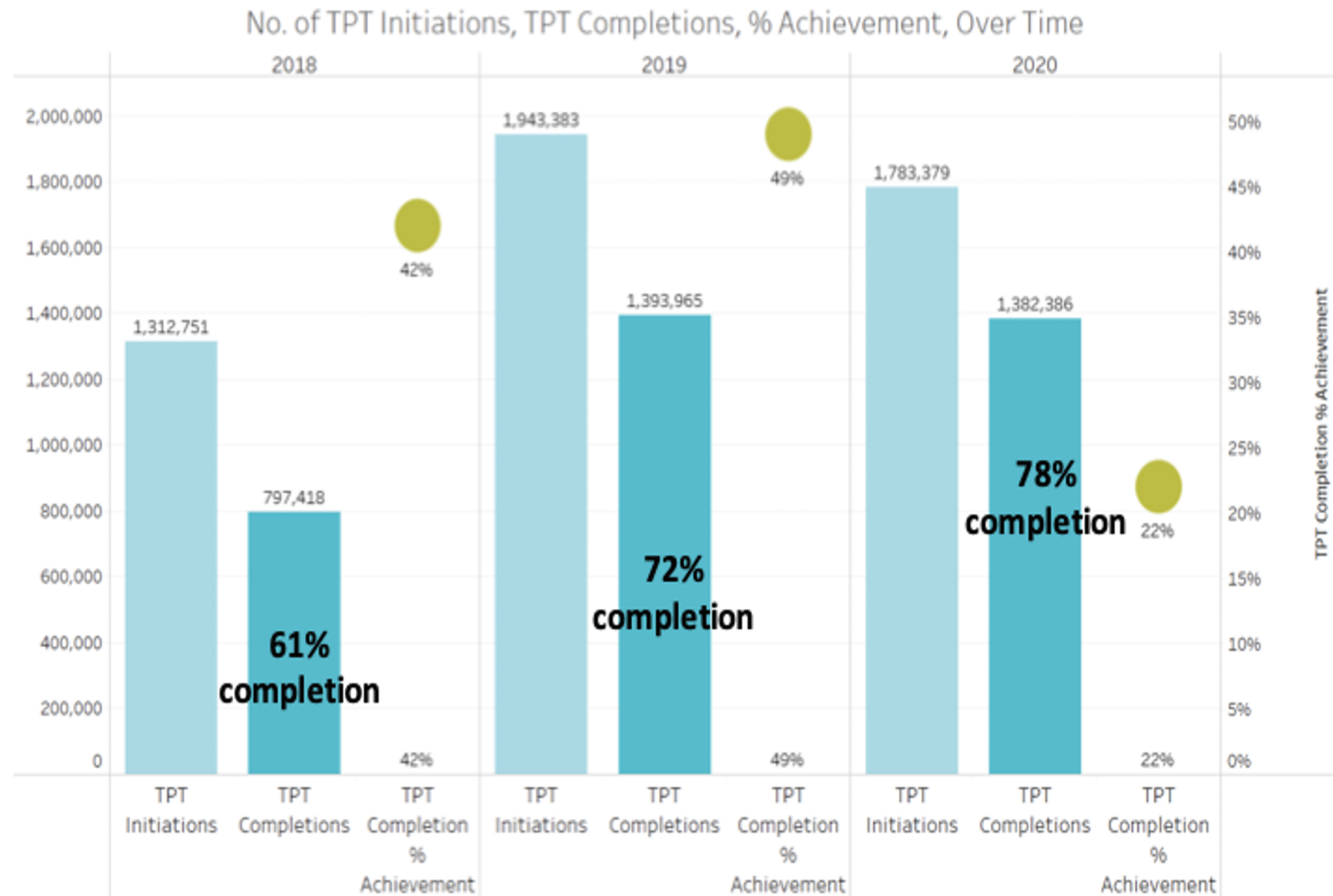
WHO 2018 Guidelines on the management of latent tuberculosis infection

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Even when prescribed...still not adequately monitored resulting in weak outcomes

PEPFAR TREND: PROMISING TPT DATA

Number of PLHIV completing TPT, 2018-2020 Q2



IMPROVED TPT REGIMENS

...shorter and 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 = 3 months of daily rifampicin (R) + Isoniazid (H)

4R = 4 months of daily rifampicin (R)

FDC of Rifapentine 300mg + Isoniazid 300mg (3HP)
Scored Tablet



Adult Dose: 3 tablets per week for 3 months (Total 36 tablets)

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

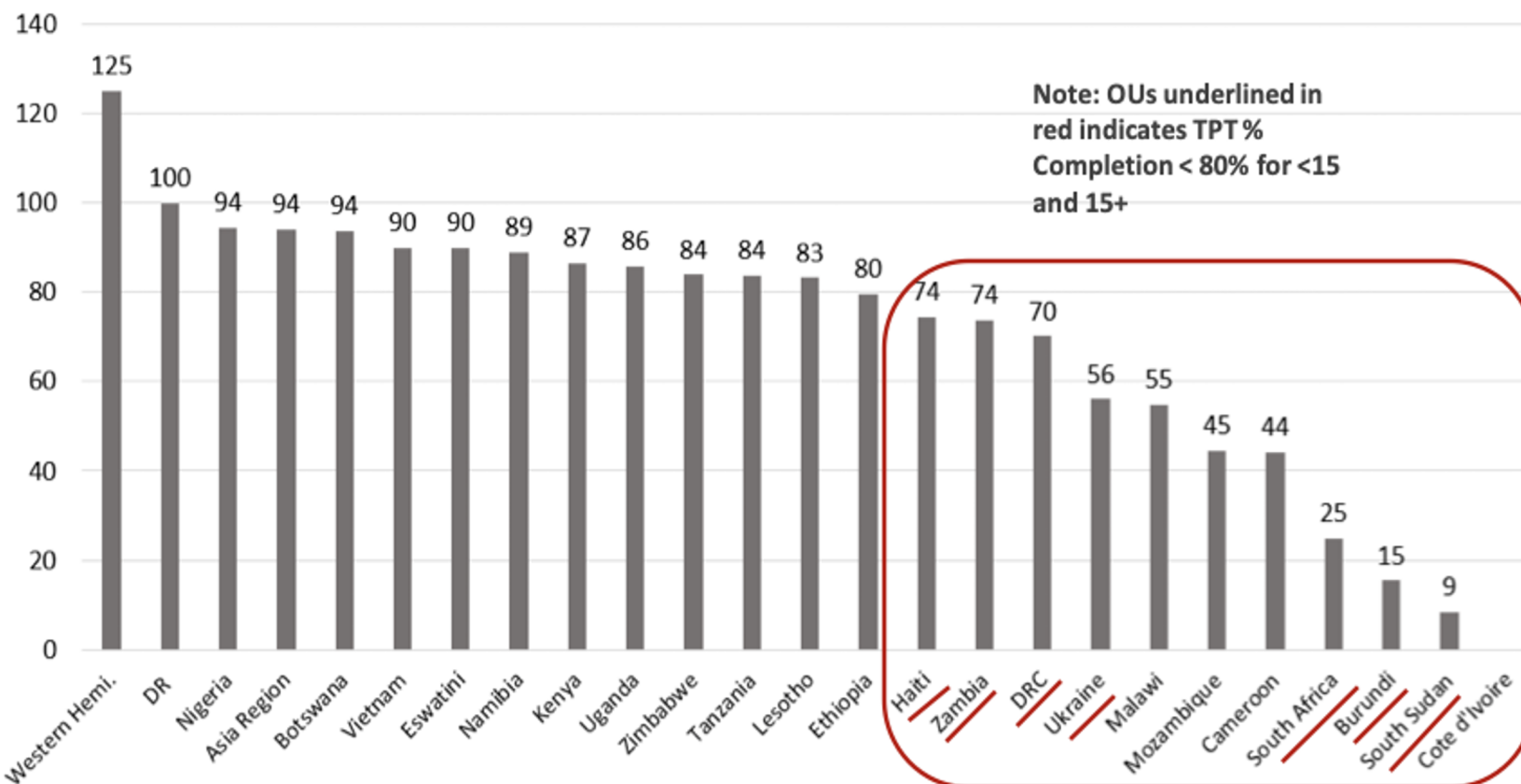
Less liver toxicity than IPT

Higher completion rates than IPT

Similar efficacy as IPT in preventing TB

SOME PEPFAR SUPPORTED COUNTRIES ARE LAGGING BEHIND

TPT Completion Among <15 (FY20 Q2): Need for greater attention



WHAT IS IN THE COP21 GUIDANCE on TPT (i)?

Minimum Program Requirement on TPT: “All eligible PLHIV, including children and adolescents, should complete TB preventive treatment by the end of COP21, and cotrimoxazole, where indicated, must be fully integrated into the HIV clinical care package at no cost to the patient”

- “If PLHIV are enrolled in a DSD program for ART, TB treatment or TPT should also be integrated into DSD. To ensure TB prevention and treatment services continuity in the context of COVID19, many countries moved into implementation of MMD for TPT and TB treatment aligned with ART MMD plans.” ****key concerns related to supply chain stability****
- “All PEPFAR-supported care and treatment programs should be fully engaged in aggressive TPT scale-up with clear timelines to 100% coverage, focusing on rifapentine-based regimens”
- PEPFAR recognizes that supply of rifapentine has been limited due manufacturing disruptions related to COVID-19, delays in ERP approval, as well as recent nitrosamine related alerts requiring additional quality control measures.

WHAT IS IN THE COP21 GUIDANCE on TPT(ii)?

- “TPT initiations slowed or were delayed in the wake of COVID-19; these countries will need to **implement aggressive TB “catch-up” plans** in order to achieve full TPT coverage.” (@Pg366)
- “...benefits and risks of **deferring TPT initiation for pregnant women based on their epidemiologic context, national guidelines, and in conversation with pregnant women.** (@Pg369) “**Treatment literacy and counseling** should be provided to empower pregnant women to decide when and whether to initiate TPT...” (@Pg370)
- “There is extensive evidence that isoniazid (**6H or 9H**) **is well-tolerated in children and adolescents**; therefore, it **should continue to be used as the regimen of choice for children pending availability of 3HP** in child-friendly formulations at an affordable price” (@Pg368)
- “PEPFAR supports **inclusion of vitamin B6 in INH-containing TPT regimens**, lack of vitamin B6 has been cited by communities as a major barrier to acceptance of TPT regimens and additional local contributors...” (@Pg370)

IMPAACT4TB UPDATES 4 COP21 ADVOCACY (i)

- The supply picture for rifapentine for the 3HP and 1HP regimens look better in 2021 than it did in 2020
- Sanofi makes rifapentine as single tablets. Macleods is introducing a new 3HP FDC that combines rifapentine with isoniazid. The introduction of the Macleods FDC is imminent.
- **Reality of 2020:** Production disruptions due to COVID-19 -identification of nitrosamines in drug product, ERP approval delays of the Macleods product
- **Plans for 2021:** Commencement of production of rifapentine and shipping of both products

IMPAACT4TB UPDATES 4 COP21 ADVOCACY (ii)

- Price agreements for rifapentine with Sanofi and Macleods remain in effect through 2021. The price of 3HP (for both Sanofi and Macleods) regimens remains ~\$15/patient course.
- Unitaid estimates that between both Sanofi and Macleods there will be global availability of at least 2 million patient courses of 3HP in 2021.

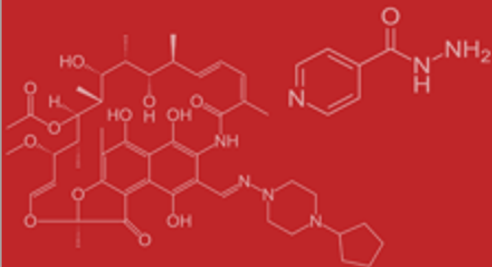
SOME DISTRIBUTION ISSUES TO LOOK OUT FOR:

- Each batch of rifapentine will be tested to ensure the level of nitrosamine is below the interim acceptable intake limits set by FDA and WHO. Advocates can ask for 3HP with assurance that its quality and safety is being systematically tested for each batch made.
- There is a need for **expedited initiation of 3HP**. The amount of nitrosamines can sometimes increase as products sit and/ or is near the end of shelf-life. Rolling out of 3HP as it lands in country should happen without long delays or periods of keeping product in central warehouses.

THE FOLLOWING ARE NON-NEGOTIABLE!!!!

1. **TPT is the cornerstone of TB prevention.** All PEPFAR programmes must scale up TPT. This is non-negotiable especially amidst this Covid-19 public health crisis.
2. Where transition from INH to rifapentine-based regimens is underway, **programmes MUST ensure that there are sufficient vitamin 6 supplies in INH/IPT programmes.** Effective monitoring of supply chains is crucial.
3. **Where DSD models exist for PLHIV,** these programmes MUST include provision of TPT (whether it be INH/IPT or the short-course rifapentine-based regimens), where supply chain allows
4. Programs MUST ensure expeditious **transitioning from INH to rifapentine-based regimens** (as per WHO guidance). **Rifapentine is now AFFORDABLE.** The supply chain & nitrosamine impurity challenges are being monitored and addressed.
5. **TPT is NOT a standalone activity.** PEPFAR programmes MUST integrate service delivery (i.e. integrated 3HP into the DTG packages & DSD models ect). **Community-Led Monitoring (CLM) strategies need to include TPT.**

Isoniazid/Rifapentine (3HP) Access Roadmap and Patent Landscape



Kindly refer to
TAG's updated
Activist's
resources on the
what, where, how
and why on 3HP.
The Activist
Guide is
available in
English,
Portuguese,
Kmher & French

LE GUIDE DU COMMUNAUTAIRE POUR LA

RIFAPENTINE

COMME TRAITEMENT DE LA TBCC INFÉCTION



HIV TB HCV PIPELINE REPORT 2018

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