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COMMUNITY ADVOCACY GUIDE ON TUBERCULOSIS PREVENTIVE TREATMENT

COMMUNITY ENGAGEMENT MATTERS TO REACH ALL PEOPLE ELIGIBLE FOR TPT.

NOVEMBER 2022

IMPAACT4TB
PREVENTING TB TO END TB

Stop TB Partnership

TB PREVENTIVE TREATMENT (TPT)?

TB Preventive Treatment (TPT) is medication given to people with inactive Tuberculosis infection (TBI) to prevent them from getting sick. Most people who breathe in TB bacteria and become infected are able to fight the bacteria to stop them from multiplying and the bacteria remain alive but inactive. This is what is called latent TB infection.

One-quarter of the world's population is estimated to be infected with the bacterium that causes TB, a disease that kills more than 4,000 people every day. Without treatment, many people with latent TB infection can develop active TB disease. Once they have active TB disease, they are at risk of death and are infectious to their close contacts such as their children, other family members and co-workers who are at high risk of getting TB. By treating the TB infection, we are able to prevent the latent TB infection from developing to active TB disease.

TPT ENSURES PEOPLE WITH TB INFECTION

- Have no symptoms
- Don't feel sick.
- Can't spread TB bacteria to others.

STATUS OF TB PREVENTION

Active TB disease remains a major global health concern, that accounted for 1.4 million deaths in 2021 and 187,000 people with HIV[1]. Globally, an estimated 10.6 million people fell ill with active TB disease in 2021, out of which 57% were men, 33% were women and 11% were children.

Globally the number of people living with HIV and household contacts diagnosed with TB infection who were provided with TPT increased from 3.2 million in 2020 to 3.5 million in 2021. The total number of people provided with TPT in 2020 was 3.2 million, a 22% reduction compared with 2019. The figure 1 below shows the global number of people provided with TPT, 2015–2020

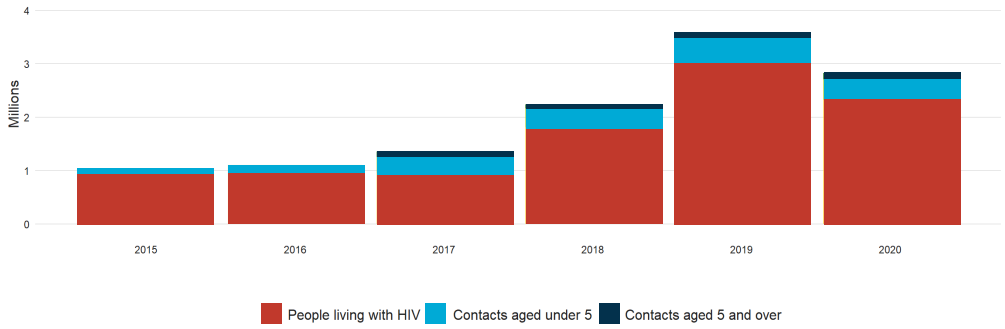


Fig.1. The global number of people provided with TB preventive treatment, 2015–2020: Source WHO

At the first United Nations (UN) high-level meeting on TB in 2018, Member States committed to a global target of providing TPT to at least 30 million people in the 5-year period 2018–2022: 6 million people living with HIV, 4 million children aged under 5 years who are household contacts of people diagnosed with active TB disease, and 20 million household contacts in older age groups[2]. At the UN high-level meeting on HIV and AIDS held in June 2021, countries committed to ensuring that 90% of people living with HIV receive

1 WHO Global TB Report 2022
2 United Nations General Assembly. Resolution 73/3: Political declaration of the high-level meeting of the General Assembly on the fight against tuberculosis. New York: United Nations; 2018 (https://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/73/3).

TPT by 2025[3]. Progress made in the past three years lags far behind that needed to reach the global target set at the UN high-level meeting on TB: the combined total of 8.7 million in 2018–2020 is only 29% of the target of 30 million for the 5-year period 2018–2022. Global indicators suggest that targets for TB preventive treatment are being largely met for people living with HIV, but we are reaching only a one third of < 5-year-old contacts and merely 2% of eligible ≥ 5-year-old contacts.

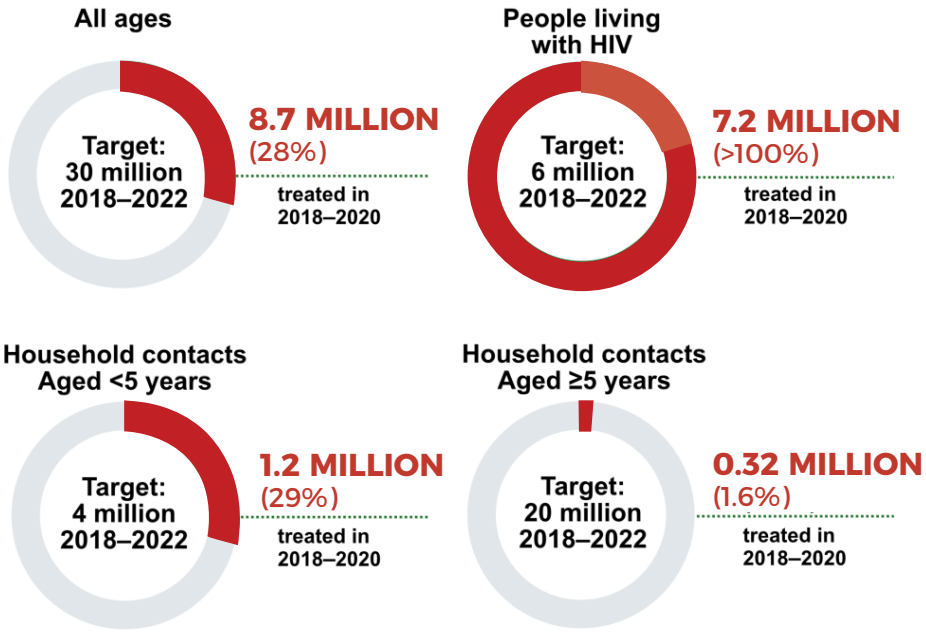


Fig. 2 Global progress in the provision of TB preventive treatment 2018–2020 compared with cumulative targets set for 2018–2022 at the UN high-level meeting on TB

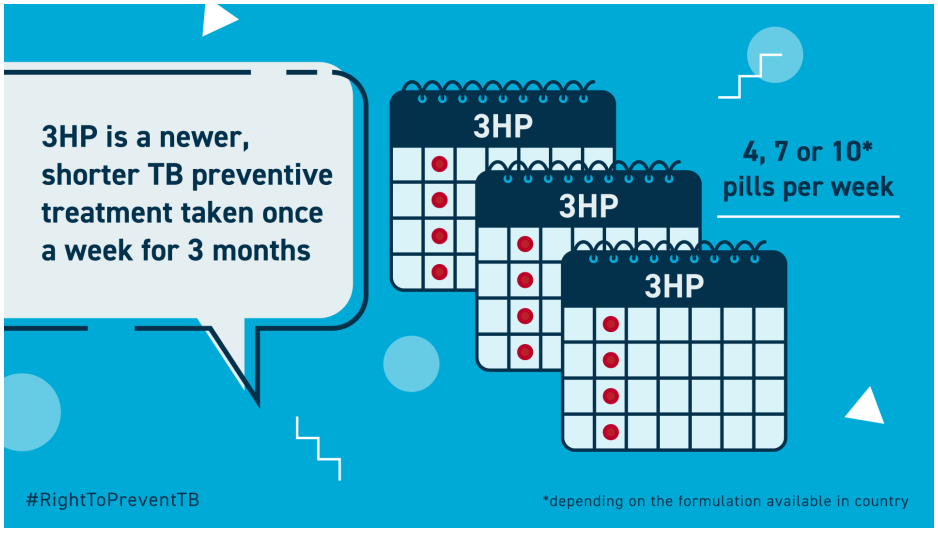
TREATMENT REGIMENS FOR TB INFECTION

Over the past decades, isoniazid preventive treatment (IPT) for six months (6H) has been the most widely used regimen under programmatic conditions among PLHIV and children < 5 years in contact with active pulmonary TB disease respectively. Several systematic reviews have consistently demonstrated the efficacy of IPT in preventing TB disease among those infected with TB.

TPT has been available since the 1960s, yet very few people who should get TPT receive it. And because IPT require daily treatment for at least six months, many who start treatment may fail to complete a full, effective course. The good news is that we now have new, shorter treatment options. In recent years, globally the evidence on efficacy and safety of newer shorter TPT regimens have been growing. WHO has recommended multiple TPT options that are equivalent and increasingly, recommend countries to move to shorter, safer, and more effective regimens. Isoniazid-based regimens however will continue to play an important role where rifamycin's cannot be used.

Short-course treatment regimens, such as 3HP, 3HR, 1HP, and 4R, are effective, safe, and have higher completion rates than longer 6 to 9 months of isoniazid monotherapy (6H/9H). Shorter, rifamycin-based treatment regimens generally have a lower risk of hepatotoxicity than 6H and 9H. If short-course treatment regimens are not a feasible or an available option, 6H and 9H are acceptable alternatives. Although effective, 6H and 9H have higher toxicity risk (especially related to the liver) and lower treatment completion rates than shorter treatment regimens such as 3HP, 3HR and 1HP.

3 United Nations General Assembly. 75th session. Item 10 of the agenda. Implementation of the Declaration of Commitment on HIV/AIDS and the political declarations on HIV/AIDS. Draft resolution submitted by the President of the General Assembly. Political Declaration on HIV and AIDS: Ending Inequalities and Getting on Track to End AIDS by 2030 (A/75/L.95). New York: United Nations; 2018 (https://www.un.org/pga/75/wp-content/uploads/sites/100/2021/06/2107241E1.pdf)



EVIDENCE ON 3HP

- Clinical trial-based evidence4 generated over the past two decades shows similar preventive efficacy with a shorter rifapentine-based TPT regimen, both in HIV-positive and HIV-negative individuals, called 3HP that combines rifapentine with isoniazid. The 3HP regimen was also associated with a higher completion rate in all adults with HIV, adults without HIV, children and adolescents.

- Two of the RCTs involved adults with HIV from South Africa, Peru and a number of countries with a TB incidence5. A systematic review of adverse events of rifapentine and isoniazid compared to other treatments for latent tuberculosis infection (23 RCTs & 55 non-randomised studies) shows lower rate of AEs with 3HP.

- No significant difference in TB incidence was found in an intention-to-treat analysis; however, a per-protocol analysis showed a lower rate of TB infection or death in participants given continuous isoniazid. In all the studies, 3HP was given under direct observation[6]. In a study of 3HP in 112 pregnant women, the rates of spontaneous abortion and birth defects were similar to those in the general population in the USA[7].

- The clear advantages of these regimens are better adherence due to the shorter duration and fewer adverse events. The use of shorter rifamycin-based regimens is associated with at least 20% greater treatment completion rate (82% vs 61%)8. IN its 2020 guidelines on TB preventive treatment, WHO assessed and recommended 3HP alongside several shorter rifamycin-based regimens (1HP, 3HR, 4R) as alternatives to six months of isoniazid.

WHY TB PREVENTION IS IMPORTANT?

Preventing TB infection and stopping progression from TB infection to active TB disease are critical to reduce TB incidence. So far, progress has mainly been hindered by a lack of political will and awareness, lack of adequate resource allocation, as well as poor innovation in service delivery and scale-up of evidence-based interventions. Insufficient awareness and leadership hinder the steps that are essential to prioritization and allocation of sufficient technical and financial resources to TPT within national TB programs as well as other relevant linked programs (especially HIV, MNCAH and nutrition).

4 Organization WH. Latent tuberculosis infection: updated and consolidated guidelines for programmatic management [Internet]. World Health Organization; 2018 [cited 2021 Feb 22]. Available at:
5 Pease C, Hutton B, Yazdi F, Wolfe D, Hamel C, Barbeau P, et al. A systematic review of adverse events of rifapentine and isoniazid compared to other treatments for latent tuberculosis infection. Pharmacoepidemiol Drug Saf. 2018 Jun;27(6):557–66.
6 WHO consolidated guidelines on tuberculosis. Module 1: prevention – tuberculosis preventive treatment. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO [Internet]. [cited 2020 Oct 30]. Available at: https://apps.who.int/iris/bitstream/ha ndle/10665/331170/9789240001503-eng.pdf. Accessed March 2021.
7 Moro RN, Scott NA, Vernon A, Tepper NK, Goldberg SV, Schwartzman K, et al. Exposure to Latent Tuberculosis Treatment during Pregnancy. The Prevent TB and the iAdhere Trials. Ann Am Thorac Soc. 2018 May;15(5):570–80.
8 Alsdurf H, Hill PC, Matteelli A, Getahun H, Menzies D. The cascade of care in diagnosis and treatment of latent tuberculosis infection: a systematic review and meta-analysis. Lancet Infect Dis. 2016 Nov;16(11):1269–78.

We need to move away from a narrow focus on treatment of active TB disease in order to end TB. Despite TB being both a curable and treatable disease, millions of people are still dying from the disease every year. It's time to revisit how we're tackling this disease, and adopt a comprehensive approach to prevention, detection and treatment.

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

This population is at risk of developing active TB disease at some point in their life. Without treatment, 5 to 10 percent of infected people or between 85 to 170 million people will develop TB disease.

TARGET POPULATIONS

To end TB, we need to stop the disease in its tracks by shielding the most vulnerable groups from progressing from latent TB infection to active TB disease.

CHILDREN UNDER THE AGE OF FIVE

Children are at highest risk of dying from tb. By treating all children under the age of five who are exposed to tb, we're stopping the next generation from dying from tb. The benefits of treatment of latent tb infection are greater in children than in adults for several reasons:

- TB infection in children younger than five years is always recently acquired (i.e., within 5 years), and recent infections have a higher likelihood of progression to disease than infections acquired less recently;
- Children have an increased risk of developing severe TB with sequela (e.g., meningitis and disseminated disease);
- Children have more years at risk for the development of TB than adults, and children tolerate treatment for LTBI better than adults.
- By keeping children healthy and allowing them to prosper and go to school, we're helping families avoid the catastrophic cost of TB.

PEOPLE LIVING WITH HIV

People being successfully treated for HIV are now dying from TB.

People living with HIV are at high risk of latent TB, but their infection often goes unnoticed and untreated until it's too late. TB is the leading cause of death among people living with HIV. People living with HIV are 20 to 30 times more likely to move from latent to active TB than those without HIV infection.

HOUSEHOLD CONTACTS (OR CLOSE CONTACTS) OF PEOPLE WITH TB.

Household contacts of those with TB (including mothers, youth, children, adolescents & adults) have a 25 times higher risk of progressing from latent to active TB than the general population.

KEY AND VULNERABLE POPULATION

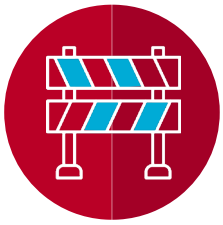
People infected with TB bacteria have a 5–10% lifetime risk of falling ill with TB. Those with compromised immune systems, such as people living with HIV, malnutrition or diabetes, or people who use tobacco and other populations who face environmental/ behavioural risks such as mining and People who use drugs have a higher risk of falling ill with TB.

BARRIERS TOWARDS ACCESSING TB PREVENTIVE TREATMENT

Prevention of new infections and their progression to TB disease is critical to reduce the burden of ill health and death caused by TB. Many in the populations most vulnerable to TB, including children, people living with HIV, and healthcare workers, lack support for the TB treatment they need. Human rights and gender related barrier such as stigma[9], discrimination, lack of information, limited health care worker buy-in,[10] and commodity insecurity due to stock outs[11] prevent accessing TPT. Improving TPT utilization requires close investigation of these factors and innovative solutions to overcome these barriers.

OVERCOMING KEY BARRIERS TO SCALE UP TREATMENT TPT

The **Global Plan to End TB, 2023-2030**[12] maps out how to end TB as a public health challenge by 2030—the year by which governments around the world committed to achieving the United Nations Sustainable Development Goals (SDGs). SDG three is to "ensure healthy lives and promote well-being for all and all ages," and one of the targets includes ending the TB epidemic. This goal was the focal point of the 2018 United Nations High-Level Meeting (UNHLM) on TB, where member states embraced several global commitments that the world currently is not on track to meet, especially because of the setback to the global TB response due to the COVID-19 pandemic. It provides a blueprint of priority actions to Scaling up TB prevention.



TPT is an essential intervention towards achieving the goals of the End TB Strategy. Its effectiveness in reducing progression from TB infection to disease ranges from 60% to 90% and protection can last many years. Despite this, global action to expand TPT has been very slow and urgent steps should now be taken to accelerate the programmatic uptake of TPT. To overcome the main barriers standing in the way of global scale-up in TPT, countries, partners, donors, and communities should work together to:

- There is need to set ambitious targets noting the position that the targets on TPT among PLHIV in the 2018 UNHLM are maybe not as ambitious as some had hoped, it may be good to make a reference to the need in this area going forward – ie. In 2023
- Safe, affordable, accessible TB vaccine should also be part of our TB prevention package
- Ensure that all TB programmes aiming to end or eliminate TB include TPT as an integral part of a comprehensive strategy
- Advocate strongly and communicate widely for TPT scaleup

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9 **https://www.hhrjournal.org/2021/12/building-the-evidence-for-a-rights-based-people-centered-gender-transformative-tuberculosis-response-an-analysis-of-the-stop-tb-partnership-community-rights-and-gender-tuberculosis-assessment/**

10 The Global Fund Assessment and best practices of joint TB and HIV applications: progress, challenges, and way forward. Geneva, Switzerland: The Global Fund; 2019. [**Google Scholar**]

11 3. Surie D, Interrante J D, Pathmanathan I et al. Policies, practices and barriers to implementing tuberculosis preventive treatment-35 countries, 2017. Int J Tuberc Lung Dis. 2019;23(12):1308–1313. [**PubMed**] [**Google Scholar**]

12 **https://www.stoptb.org/global-plan-to-end-tb/global-plan-to-end-tb-2023-2030**

PRIORITY ACTIONS			
Implement airborne infection prevention and control measures in health care settings and high-risk indoor places where people congregate.	Provide TPT for those living with TB infection and who are at higher risk of progression to active TB disease.	Deploy effective vaccines once such vaccines are officially recommended and available.	Address TB risk factors and social determinants.

- Strengthen contact investigation in the community and in households of people with active TB especially in the current context of the COVID-19 pandemic
- Initiate contacts of all ages on TPT after TB disease is ruled out
- Expand TPT in HIV services and in facilities caring for other people eligible for TPT
- Develop capacity to test for TB infection and to exclude TB disease
- Provide better tolerated and shorter TPT options on a large scale
- Ensure adherence and completion of the full course of TPT
- Collect data on contact investigation, and the initiation and completion of TPT to monitor programme performance

THE ROLE OF CS, TB SURVIVORS AND ADVOCATES

Civil society (CS) and affected communities are key stakeholders in the efforts for ending TB including TPT. While providing TPT is primarily a responsibility of health services, it is acknowledged that the role of CS and communities is to facilitate demand generation and appropriate health-seeking behaviour of people who can benefit from TPT. CS has been and continues to be actively involved in every phase of the TB response, across the continuum of care, from advocacy to service delivery, from policy to program design, from implementation to monitoring and evaluation. Civil society and community advocacy are essential for the elimination of TB. CS, TB Survivors, and Advocates can;

1. Create awareness within communities on TB in order to generate demand for TPT as there is a clear lack of knowledge among community members about the recognized benefits of TPT and actions are required from individuals, families and communities for the effective implementation of the same.
2. Inform community about benefits of TPT to individuals, families, and community by emphasizing how TPT acts as prevention and how it can break the transmission chain of TB in the community.
3. Consult the community for planning, implementing, and monitoring the TPT intervention and scale-up.
4. Empower affected community as a partner in TPT response through capacity building and involvement of TB survivors, their contacts & others who are eligible for TPT and networks of TB survivors in various facets of the response at each level.
5. Ensure that TB remains in the global, regional and national agendas and call for urgent investments in TPT;
6. Act on TPT related commitments made by national leaders and head of states during high-level intergovernmental forums
7. Engage policy-makers (including ministers of health, finance and foreign affairs and members of Parliament) to develop sustainable approaches to prevent and tackle TB;
8. Monitor global and local supply chains to avert shortages and stockouts of TPT drugs, especially the drug rifapentine which is central to the 3HP and 1HP regimens;
9. Providing peer counselling with psycho-social support, addressing of self- stigmatization, etc. to the client on treatment for active TB disease and his/her family members.
10. Ensuring supportive monitoring of those on TPT and providing of treatment education, suggestions on nutrition, healthy lifestyles and positive living, psychosocial support, addressing specific issues during home visits, etc.

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- IMPAACT4TB; **https://www.impaact4tb.org/**
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CONTACT US

Plot # 595, Njiro Nanenane, Mwakalinga Road, Off Njiro Road, 23109 Themi Mashariki

P.O. Box 6187, Arusha, Tanzania

: +255 739 210598 eannaso@eannaso.org

www.eannaso.org | eannaso | facebook.org/eannaso.org