

TB Preventive Treatment Budgeting Tool: Background Document

Globally, almost 1.7 billion people are infected with latent TB, which can remain dormant for decades, and about 5%–10% of these infected people remain at risk of developing active TB. People who are living with TB-infected individuals have 25 times higher risk of progressing from latent TB to active TB than the general population. Children younger than age 5 are at highest risk of progression to active TB. People living with HIV are also among the high-risk population group of disease progression. Adopting a comprehensive approach to TB prevention, detection, and treatment is necessary for TB control. The goal of a TB preventive treatment (TPT) investment at the country level is to identify household members who have been exposed to TB but are healthy *in order to provide preventive treatment* and avert disease. In all instances this should include children younger than 5 and persons living with HIV. According to national guidelines this may include other household members as well (and reference the new WHO TPT guidelines).

The purpose of this budgeting tool is to support planning and budgeting for the roll-out of TPT services in high-TB-prevalence settings. This summary and the TPT budget estimation tool can assist countries to make budgets needed to support TPT activities within their overall TB, maternal and child health, and/or HIV programs. The tool does not include diagnostic costs or other general TB-related health system costs. These costs (human resources [HR], pharmacy, infrastructure, and monitoring and evaluation [M&E]) are assumed to be costed in general budget areas.

This tool may be used in conjunction with the Household Contact Investigation budgeting tool, which will help estimate the costs of the Household Contact Investigation for TB prevention programs.

This budgeting tool is focused on the following target populations as they represent the highest-risk groups for becoming infected with TB:

- ❖ People living with HIV
- ❖ Children younger than 5 years who are household contacts (HHCs) of people affected by active TB disease

HHCs older than 5 years of age should be included if national guidelines for TPT recommend this as a target population for TPT.

When planning for the roll-out of TPT, the following are the key issues that should be taken into consideration:

- ❖ Eligibility criteria for TPT in people living with HIV, HHCs older than 5 years of age, and pregnant women

- ❖ Service delivery models
- ❖ Supply planning during the scale-up of new short-course regimens

In March 2018, *WHO recommended several new short-course latent TB infection (LTBI) treatment options*, including rifapentine plus isoniazid given weekly over three months (3HP) and rifampicin plus isoniazid daily for three months (3RH), in countries with high TB incidence.

- ❖ The 3HP regimen is as safe and effective as other recommended TPT regimens and achieves significantly higher treatment completion rates. The regimen was shown to be as efficacious, but with a significantly lower risk of hepatotoxicity and higher completion rates, when compared to the isoniazid nine-month treatment. 3HP is available in a fixed-dose combination of 300 mg isoniazid and 300 mg rifapentine for people weighing more than 30 kg and also as single-tablet of 300 mg isoniazid and 150 mg rifapentine (Priftin®).
- ❖ 3HP currently can be used only in patients on efavirenz and adults on dolutegravir (DTG) and not in those on nevirapine and protease inhibitors as no data are available to confirm their efficacy with patients receiving those drugs. Administration of 3HP with DTG was found to be safe and well tolerated.
- ❖ 3HP can be administered to patients receiving efavirenz-based antiretroviral regimens without dose adjustment.
- ❖ DTG can be given with 3HP without dose adjustment in stable adults living with HIV who are on antiretroviral therapy (ART) and are virally suppressed, according to recent findings from the DOLPHIN trial. 3HP cannot be used in children living with HIV who are younger than 15 and are on DTG.
- ❖ There are limited data to support co-administration of 3HP and ART in ART-naïve people living with HIV; this will be studied under the DOLPHIN trial extension, DOLPHIN Too.
- ❖ 3HP is not currently recommended for use during pregnancy due to the lack of supporting data.
- ❖ 3HP can be given to children 2 years and older. A child-friendly formulation is currently being studied (TBTC Study 35) for children younger than 12 years of age.
- ❖ 3RH should be offered as an alternative to six months of isoniazid monotherapy as preventive treatment for children and adolescents. Children weighing less than 25 kg (about 8 years of age) should receive the rifampicin/isoniazid 75 mg/50 mg dispersible tablet as an FDC.

The costing of program management for LTBI involves identifying those individuals who should be screened for TB (i.e., contact investigation activities), performing TB screening activities, delivering effective and safe treatment, and M&E of the process and outcome. The tool is divided into four sections:

- ❖ Sections 1 and 2: summary and instructions
- ❖ Sections 3 and 4: drug costs (all regimens including new short-course regimens 6/9 INH, 3HP, 1HP, 3RH, and 4R)
- ❖ Section 5: children younger than 5 (including HR, training, M&E, adherence programs)
- ❖ Section 6: people living with HIV (including HR, training, M&E, adherence programs)

Country-specific Factors That Affect the Cost of TPT Activities

Please consider these factors as you are estimating needs for TPT scale-up. Knowing these considerations will aid in planning, assist in completing the budget tool, and help to generate accurate budget estimates.

1. Country-specific national guidelines (as related to TPT)
 - a. Which eligibility criteria are in place (inclusion and exclusion)
2. Estimated newly initiated on ART, current on ART, and children younger than 5 in high-TB-burden settings
 - a. Available in country-specific demographic/health/household surveys
3. Country-specific TB epidemiology
 - a. TB incidence and proportion of various TB disease types
4. Program plans for TPT
 - a. Preferred/required cadre of health care workers (HCWs) to deliver TPT in facilities or as part of differentiated care
 - b. Number of districts/sites or TPT uptake in each year of the Global Fund funding cycle
5. Number of clinics treating index people living with HIV/receiving household referrals from contact investigation activities
 - a. Indirect staff time/costs—can include community health workers' estimated time/costs
6. Communication needs
 - a. SMS or other phone-based communications for patient follow-up
7. Data system(s)
 - a. Paper-based tools versus electronic tools for use in the field
 - b. Needed updates to electronic reporting systems
 - c. Personnel to support M&E

Individual Items for Cost Estimates Needed for TPT Programs at Facility Level

1. Personnel
 - a. Personnel for service delivery
 - b. Personnel for M&E
 - c. Personnel for pharmacy
 - d. Personnel at NTP/NHAP/NMCH level

2. Transport
 - a. Personnel transport to/from household to start TPT
 - b. Patient transport to facilities for further workup/needs (if covered/subsidized)
3. Personnel training and support
 - a. Training required for HCWs on TPT regimens and procedures
 - b. Job aids to be used by HCWs during TPT demand creation
4. Community sensitization for demand creation
5. M&E
 - a. Printed registers
 - b. Updated electronic TB reporting system to include contact tracing data

Additional TB Programming Areas That Are Required for Successful Implementation of TPT and Cascade of Cares but That Have Not Been Included in This Tool

1. Contact Investigation activities (not included in this tool but included in the HHC investigation budgeting tool)
2. Cost for diagnosis of TB infection (not included because tests for TB infection are not recommended for the high-risk groups)
3. Cost for diagnosis or rule-out of active TB disease for symptomatic individuals (i.e., chest X-ray, tests for lab-based diagnosis, HR for lab-based diagnosis, sample transportation)
4. Cost for treatment of active TB disease
5. Supply chain management costs
6. People living with HIV outreach program for TB coinfecting

Please see annex 1 for specifics about drugs and dosing along with an LTBI brief on 3HP versus 3HR by Aurum's IMPAACT4TB and Elizabeth Glaser Pediatric AIDS Foundation's CAP-TB projects at https://www.impaact4tb.org/wp-content/uploads/2019/06/LTBIBrief_0607.pdf.

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