World Health Organization

REGIONAL OFFICE FOR South-East Asia

A SITUATIONAL ANALYSIS OF

PROGRAMMATIC MANAGEMENT OF TB PREVENTIVE TREATMENT

IN THE WHO SOUTH-EAST ASIA REGION

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A situational analysis of programmatic management of TB preventive treatment in the WHO South-East Asia Region

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FOREWORD

The WHO South-East Asia Region continues to accelerate efforts towards ending TB by 2030, for which all high-risk individuals require access to TB preventive treatment (TPT). TB infection, which is a precursor of TB disease, is extremely common in the Region, with an estimated 30% of the Region's population infected with TB bacteria. Global and regional scientific evidence clearly indicate that the burden of TB cannot be reduced unless we prevent the disease in individuals at high risk of progression from TB infection to disease. Such individuals include household contacts of persons with infectious TB disease, people living with HIV and other high-risk groups whose immunity is compromised.

TPT is a cost-effective way of reducing the risk of TB infection from progressing to TB disease. WHO has developed guidelines and operational handbooks to support the uptake and scale up of TPT services. To add momentum and urgency to the implementation of TPT, in September 2018, at the first ever UN High-Level Meeting on TB, all country leaders pledged to provide TPT to at least 30 million people at risk of TB disease between 2018 and 2022. In the same year, WHO, in consultation with stakeholders, supported the development of a regional action plan to support the adoption of TPT among Member States and to meet the global commitments in the provision of TPT to individuals at high risk of TB disease.

This situation analysis, undertaken by WHO in 2020, assesses the progress made in eight countries in the Region with regard to the adoption and implementation of the latest TPT policies. The analysis highlights two key findings. First, countries in the Region have provided TPT to 1.2 million high risk individuals, which is a significant achievement. But at the current pace of progress, the Region is unlikely to achieve the target of providing TPT to at least 10.8 million high risk individuals by 2022. Second, almost all countries in the Region have adopted or are in the process of adopting the latest WHO guidelines on TPT. But fully implementing the guidelines requires focused attention and coordinated action from all stakeholders, especially given the emergence and spread of COVID-19, which provides TB progammes additional challenges that we can – and must – overcome.

I call upon all Member States, partners, communities and stakeholders to prioritize the provision of person-centric TPT service delivery models that are suitable to the country context, and to allocate the resources required to rapidly scale up TPT services to End TB in the Region. Together we must continue to push ever harder to protect our many gains and to deliver on the Region's Flagship Priority on accelerating efforts to End TB, for a healthier, more sustainable future for all.

Dr Poonam Khetrapal Singh
Regional Director
WHO South-East Asia Region

ABBREVIATIONS

1 HP	isoniazid and rifapentine daily for one month (TPT regimen)
3 HP	isoniazid and rifapentine weekly for three months (TPT regimen)
3 HR	isoniazid and rifampicin daily for three months (TPT regimen)
4 R	rifampicin daily for four months (TPT regimen)
6 H	isoniazid daily for six months (TPT regimen)
9 H	isoniazid daily for nine months (TPT regimen)
36 H	isoniazid daily for 36 months (TPT regimen)
ART	anti-retroviral therapy
DPRK	Democratic People's Republic of Korea
GDF	Global Drug Facility
GF	Global Fund (for AIDS, TB and Malaria)
IGRA	interferon-gamma release assay
IPT	isoniazid preventive treatment
JMM	joint monitoring mission
LTBI	latent TB infection
MDR-TB	multidrug-resistant TB
Mtb	Mycobacterium tuberculosis
NA	not applicable
NR	not reported
NSP	national strategic plan
NTP	national tuberculosis programme
PLHIV	people living with HIV/AIDS
Q-TIB	isoniazid, co-trimoxazole, pyridoxine daily for six months (TPT regimen)
RAP	regional action plan (refers to Regional Action Plan for programmatic management of latent TB infection)
SEA Region	South-East Asia Region
SEARO	Regional Office for South-East Asia (of WHO)
TB	Tuberculosis
TBI	TB infection
TPT	TB preventive treatment
TST	tuberculin skin test
UNHLM	United Nations High-Level Meeting (TB)
WHO	World Health Organization
WHO-CO	WHO-country office

EXECUTIVE SUMMARY

Tuberculosis (TB) prevention is essential for reaching the End TB targets in the South-East Asia Region (SEAR) of World Health Organization (WHO)[1]. The targets of 80% reduction in TB incidence rate and 90% reduction in TB mortality by 2030 (compared to 2015 levels) can be achieved only with additional interventions aimed at preventing TB, according to epidemiological modelling studies commissioned by the WHO South-East Asia Regional Office (WHO SEARO). Optimal implementation of TB preventive treatment (TPT) is a critical intervention to accelerate reduction in TB burden in the SEA Region, which bears nearly 43% of the global TB burden. TPT by itself has the potential to reduce the overall annual TB incidence rates by 8.3% (95% CrI 6.5–10.8) relative to 2015.

The targets agreed upon by the Member States during the 2018 United Nations High-Level Meeting (UNHLM) on TB include improving TPT coverage as an essential component. The apportioned target for the SEA Region is to provide TPT to at least 10.8 million high-risk individuals between 2018 and 2022. High-risk individuals mainly include household contacts of infectious TB patients (disaggregated by less than 5 years and 5 years and above), and people living with HIV/AIDS (PLHIV). A 'Regional action plan (RAP) for programmatic management of latent TB infection (LTBI)' was developed by WHO SEARO in 2018 in consultation with all countries and stakeholders to ensure TPT scale-up in line with the UNHLM targets by 2022 and the End TB strategy targets by 2030 in each of the SEA Region countries.

To assess the progress in TPT implementation, a situational analysis was undertaken by WHO SEARO in the second quarter of 2020 covering eight countries (Bangladesh, Democratic People's Republic of Korea, India, Indonesia, Myanmar, Nepal, Thailand, Timor-Leste). The objectives were to describe the progress made in TPT coverage among household contacts in 2019 when compared with 2018; to assess the progress made in adopting/adapting the latest WHO recommended policies on TPT, and to identify the major challenges and opportunities for TPT scale-up in SEA Region. The analysis

Important milestones and targets to be achieved through TPT in SEA Region

Agreed that TPT coverage is important	Developed Regional Action Plan to meet the UNHLM targets by 2022	By 2019 atleast 0.9 million people initiated on TPT	TPT to 10.8 million high-risk individuals between 2018–2022	End TB strategy targets
2018	2018	2019	2022	2030

[1] WHO-SEAR consists of 11 countries: Bangladesh, Bhutan, Democratic People's Republic of Korea (DPRK), India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand and Timor-Leste.

included a review of data submitted by the countries to WHO for the Global TB Report 2019 and 2020, the latest versions of the national strategic plans (NSPs), Global Fund applications, joint monitoring mission (JMM) reports, and key informant interviews with a sample of the WHO country office TB focal persons.

Overall, in the SEA Region, 1.2 million high-risk individuals (household contacts and PLHIV) were initiated on TPT during 2018 and 2019. This is 11% of the TPT target for the Region to be achieved by 2022, as per the UNHLM commitments. In 2018 and 2019, TPT among household contacts was provided mostly to children aged less than 5 years in whom the coverage has improved from 26% in 2018 to 33% in 2019. The TPT coverage among household contacts aged 5 years and above was negligible. However, TPT coverage among PLHIV newly enrolled for HIV care doubled from 15% in 2018 to 32% in 2019 due to increased coverage in India and Myanmar. At the current pace of implementation, the regional TPT target for PLHIV is likely to be achieved by 2022 but the targets for household contacts are likely to be missed.

In 2020, national TB programmes (NTPs) of seven countries (Bangladesh, India, Indonesia, Myanmar, Nepal, Thailand and Timor-Leste) out of eight countries included in the situational analysis have revised their NSPs and have updated their TPT policies. Adolescents and adult household contacts of bacteriologically confirmed TB patients have been covered in the expanded target groups for TPT by all seven countries. Five countries have also included other high-risk clinical groups recommended by WHO in their TPT target population.

In all seven countries, the assessment for TPT eligibility in the target groups is in line with the algorithms suggested in the latest "WHO consolidated guidelines on tuberculosis: tuberculosis preventive treatment". Availability and accessibility of chest radiography and TB infection (TBI) tests are unlikely to be a major barrier for TPT scale-up as these tests are optional. However, the success of this approach is dependent on good TB symptom screening practices to prevent persons with TB disease from incorrectly receiving TPT. The seven countries have now endorsed at least one of the four shorter TPT regimens into their national guidelines; most commonly the rifapentine based 3 HP regimen.

The TPT related recording and reporting systems in all countries are part of the routine TB surveillance systems. However, there seem to be gaps in the data recorded and reported both in terms of completeness and accuracy. In all countries TPT care cascade analysis is not being done routinely to assess the adequacy of TPT uptake and completion in target groups. All countries are yet to assess if TPT related adherence and adverse drug effect monitoring and management mechanisms are adequate, patient-friendly and update them (wherever required) to ensure optimal TPT completion rates.

Several national and international technical partners are involved in supporting the respective NTPs in planning and delivery of TPT services in all countries. However, engagement with the TB affected community for TPT scale-up is inadequate at the country level. Capacity building of health system staff for optimal delivery of TPT services as per their respective

their national guidelines is yet to be completed in all countries.

The major constraints for TPT scale-up are a) inadequate focus of NTPs on TPT implementation, its supervision and monitoring; b) incomplete and/or inaccurate data on TPT coverage and non-availability of data on TPT completion due to deficiencies in recording and reporting systems; c) issues with availability and affordability of rifapentine for its usage in shorter TPT regimen commensurate to the need; d) inadequate collaboration/communication between TB and HIV programmes on the TPT component; e) inadequate training and sensitisation of health care personnel (including doctors and peripheral health staff) on the latest TPT guidelines and the operational aspects related to optimal implementation of TPT; f) inadequate communication and social mobilisation activities to educate the community and to improve demand for TPT from the community.

The key recommendations to all stakeholders involved in TPT scale-up in the SEA Region are to: a) ensure adequate importance is given for TPT scale-up by the NTPs and necessary resources are allocated to achieve the desired coverage levels at the earliest; b) promote adoption of "cascade of care analysis" as a means for assessing and improving TPT coverage in the target populations by aligning the recording, reporting, supportive supervision and monitoring systems; c) encourage operational/implementation research to identify and address gaps in the cascade of TPT care; d) ensure availability of adequate quantities through appropriate quantification and robust supply chains; e) advocate with drug manufacturers, for price reduction of rifapentine; f) develop tools for training and sensitisation of all categories of health personnel on the latest national and international TPT guidelines, and also for the development and implementation of TPT related national advocacy, communication and social mobilisation plans to increase community engagement and demand for TPT.

The COVID-19 pandemic and its impact on TPT services

Disruptions in the functioning of public health systems caused by COVID-19 pandemic have had a profound effect on TB services in the SEA Region. Several countries in the SEA Region are witnessing up to a 30% decline in the TB case notification in 2020 *(1)*. This reduction will affect the provision and scale-up of the TPT services especially to household contacts (as the number of people eligible to receive TPT is dependent on the number of bacteriologically positive pulmonary TB patients detected). Moreover, countries may also prioritise TB diagnosis and treatment services over the provision of TPT services, and in case if this happens, the progress in TPT services in the Region may not be sustained. Therefore, it is critical to advocate and ensure that TPT services are not side-lined amidst this crisis, and adequate focused attention is given to TPT.

1. INTRODUCTION

An estimated 10 million people developed TB disease in 2019, and 1.4 million died from it *(1,2)*, making TB one of the top ten causes of morbidity and mortality in the world.

TB is caused by *Mycobacterium tuberculosis* (Mtb), that spreads from person to person through airborne route. When a person with pulmonary TB coughs or sneezes, particles containing Mtb are expelled into the air and inhalation of this contaminated air may cause TBI. Once infected, about 5–10% of the people develop TB disease in their lifetime, with the risk of developing the disease being highest in the first two years of infection *(3)*. About 1.7 billion people or 23% of the world's population are estimated to be infected with Mtb, of which 55.5 million (0.8% of the world's population) are infected recently and at high risk of progression to TB disease *(4)*.

Household contacts and people living in congregate settings are at increased risk of TBI. Children, elderly, persons with undernutrition, HIV infection, diabetes mellitus, tobacco smoking, alcohol misuse and/or on immune-suppressive therapy are at increased risk of progression from TBI to disease. The high-risk groups within countries vary according to the socio-economic, demographic and epidemiological characteristics of the country's population.

Globally, all countries have committed to drastically reduce the TB burden by 2030 by adopting the WHO recommended End TB Strategy and its targets *(5)*, which were adopted by the World Health Assembly in 2014. This requires reducing the global TB incidence rate by 80%, reduction in the number of TB deaths by 90% by 2030 when compared to 2015 and ensuring that by 2020 and beyond, 0% of the TB affected families incur catastrophic costs.

Ending TB requires at least two essential public health actions to be efficiently implemented at the ground level. First, every individual who develops TB disease must be diagnosed and treated as early as possible. This leads to reduction in morbidity and mortality among the diseased individuals and reduces the risk of Mtb transmission among close contacts in the community. Second, individuals with high risk for TBI and progression from infection to disease must be identified and provided medications to prevent TB [also known as "TB Preventive Treatment" or TPT *(6)*].

Historically, in high burden low resource settings, TB control efforts were focused on early diagnosis and treatment of persons with TB disease. However, it is now being increasingly recognised that TPT is vital for reducing TB incidence in both high and low burden settings by preventing the development of the disease and hence, also its spread. This is reflected in the WHO's End TB Strategy which emphasises the provision of TPT to persons at high risk of TB under its first pillar of patient-centred care and prevention *(5)*.

To add momentum and urgency to the implementation of TPT, in September 2018, all country leaders made a commitment at the first ever UNHLM on TB, to provide TPT to at least 30 million people at risk of TB disease between 2018 and 2022 *(7)*. This included 4 million children aged less than 5 years, 20 million other household contacts of people with TB disease and 6 million PLHIV.

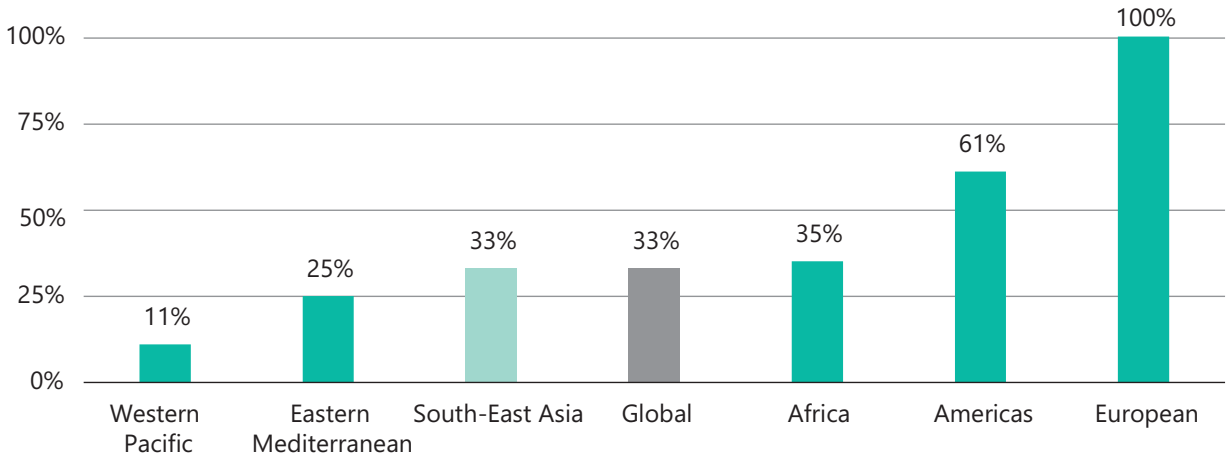
SEA Region, with only 26% of the world's population, has the highest TB incidence than any other WHO regions. In the year 2019, in SEA Region, about 4.3 million persons developed TB disease and 0.65 million persons died due to the disease *(1)*. These numbers constitute ~43% of the global TB incidence and 46% of the global TB deaths. SEA Region also has the highest proportion (30%) of people with TBI *(4)*. SEA Region countries have pledged to End TB in their respective countries in line with the WHO's End TB strategy targets and have also made the commitments towards achieving 2018 UNHLM declaration, by diagnosing and treating 18 million TB patients and providing TPT to at least 10.8 million high-risk persons between 2018 and 2022, with the numbers diagnosed and treated and numbers on TPT apportioned to each country.

A recent modelling study indicated that optimal implementation of TPT alone in the identified high-risk groups (PLHIV and household contacts) has the potential to reduce the annual TB incidence rate in the SEA Region by 8.30% (95% CrI 6.48–10.83) relative to 2015. *(8)*. This along with another modelling based study has indicated that TB disease prevention is essential to reach the End TB targets in the SEA Region *(9)*.

On their part, the SEA Region countries have made commendable progress towards reducing the TB burden by increasing the number of TB patients diagnosed and treated from ~2.6 million in 2015 to ~3.6 million in 2019 (a 38% increase) (1,10). Close to 70 000 rifampicin resistant/ multidrug-resistant TB (MDR-TB) patients were detected in 2019, more than double the number of 32 000 patients detected in 2015 *(1,10)*. But the coverage of TPT in the SEA Region remains low. In 2019, about 33% of the children less than 5 years who are household contacts of persons with infectious TB disease and 32% of the PLHIV newly initiated on HIV care received TPT **(Figure 1, Figure 2).**

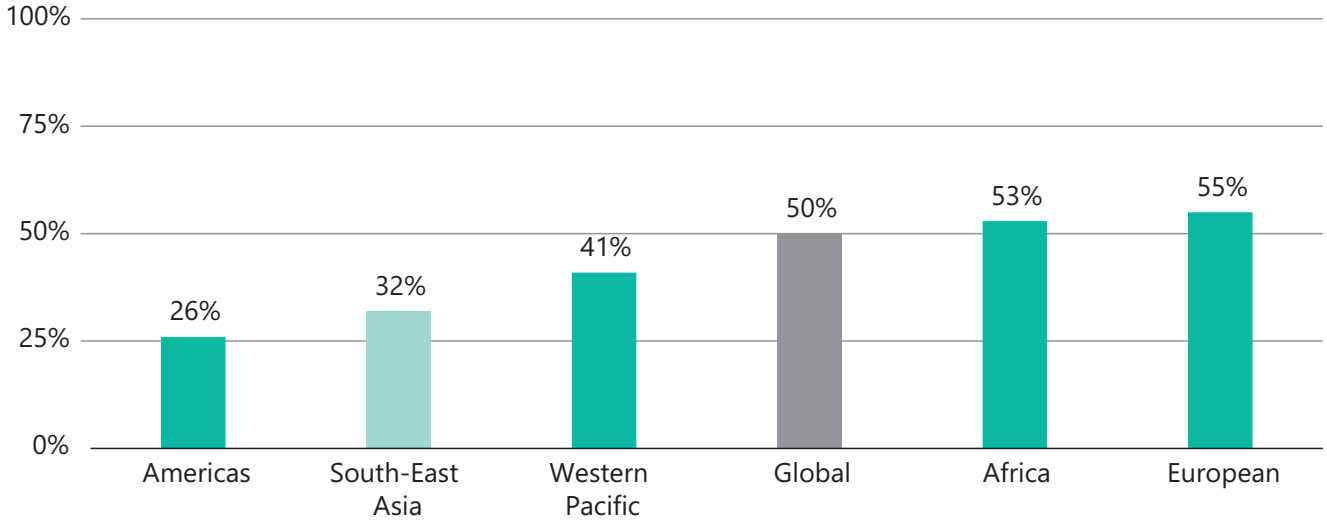
To support planning and implementation of TPT in SEA Region countries, in 2019, WHO

Figure 1: Coverage of TPT among household contacts aged less than 5 years in various WHO Regions in 2019



Source: Global TB Report 2020 *(1)*

Figure 2: Coverage of TPT among PLHIV in various WHO Regions in 2019



Source: Global TB Report 2020 *(1)*

Note: The percentage coverage data includes data for those who were newly enrolled into HIV care and from only those countries that have reported on the coverage.

SEARO in consultation with stakeholders (NTPs, civil society partners, and technical experts) developed a regional action plan (RAP) for the programmatic Management of LTBI *(11)* – in line with WHO's latent tuberculosis infection: updated and consolidated guidelines for programmatic management that was published in 2018 *(12)*.

This RAP provides guidance on the country level TPT policies and plans needed to provide quality assured TPT services to the most "at-risk" populations. During the development of the RAP country-wise targets based on UNHLM commitments were also developed **(Table 1)**. In line with the UNLHM commitments, countries of SEA Region are collectively expected to provide TPT to at least 10.8 million high TB risk individuals between 2018 and 2022, of which, nearly 8% (0.9 million) needed to be achieved in 2018–2019 itself *(11)*.

Table 1: Country-wise minimum UNHLM targets for high-risk individuals to be given TPT for the period 2018–2022 and 2018–2019

Country	TPT targets for the years 2018–2022 (Five years)				TPT targets for the years 2018–2019 (Two years)			
	Household contacts aged less than 5 years	Other household contacts	PLHIV	Total	Household contacts aged less than 5 years	Other household contacts	PLHIV	Total
Bangladesh	203 371	644 059	9302	856 732	56 542	54 326	1850	112 718
Bhutan	470	1550	675	2695	125	120	90	335
DPRK	52 117	261 896	-	314 013	20 982	23 668	-	44 650
India	1 048 290	3 863 589	1 122 183	6 034 062	213 143	150 000	103 926	467 069
Indonesia	218 192	1 282 328	817 964	2 318 484	34 875	92 000	55 707	182 582
Maldives	128	350	18	496	34	50	3	87
Myanmar	44 311	235 328	252 561	532 200	3034	22 000	14 304	39 338
Nepal	19 484	61 050	27 668	108 202	3113	8500	5 412	17 025
Sri Lanka	4406	27 980	770	33 156	1304	2500	684	4488
Thailand	18 516	235 328	362 769	616 613	1979	22 000	20 512	44 491
Timor-Leste	6 143	11 500	440	18 083	2403	1500	100	4003
Total	1 615 428	6 624 958	2 594 350	10 834 736	337 534	376 664	202 588	916 726

Source: Targets estimated by WHO SEARO in consultation with countries of the Region

In this context, a situational analysis was undertaken between April–July 2020 to assess the progress made by SEA Region countries with respect to improving TPT coverage in 2019 when compared to 2018 and the changes in the TPT policies.

2. SITUATIONAL ANALYSIS OBJECTIVES

The objectives of this situational analysis were:

1. To assess the progress made in the coverage of TPT among household contacts (especially in children less than 5 years of age) and PLHIV

2. To describe the latest TPT related policies adopted by SEA Region countries and the related changes in the components of the programmatic management of TPT

3. To outline the key challenges and opportunities and offer recommendations to improve the TPT coverage in SEA Region.

3. METHODOLOGY

The situational analysis included eight countries in SEA Region. These countries are: Bangladesh, DPR Korea, India, Indonesia, Myanmar, Nepal, Thailand, and Timor-Leste.

A semi structured checklist (Annexure 1) was developed, to guide data collection on the latest TPT policies and components of the programmatic management of TPT.

Data collection included a desk review of the following:

- Data submitted by the countries to WHO for the Global TB Report 2019 and 2020
- National strategic plans (NSPs)
- Global Fund applications
- Joint monitoring mission (JMM) reports.

The documents that were available and reviewed are listed in Annexure 2.

The initial desk review was followed by interviews with WHO country office (WHO-CO) TB focal persons to fill the gaps in the understanding of various components of the TPT using a generic interview guide (Annexure 3) with additional country specific probes.

4. FINDINGS

4.1 STATUS AND PROGRESS OF TPT COVERAGE AMONG HOUSEHOLD CONTACTS

The data reported by the eight countries for the WHO's Global TB Report 2020 *(1)* regarding the status of TPT coverage in 2019 among household contacts are given in **Table 2**.

Data on the number of new and relapse bacteriologically confirmed TB patients, number of household contacts of new and relapse bacteriologically confirmed TB patients, and the number of household contacts evaluated for TB disease and TBI in five out of eight countries, were available from the routine recording and reporting (surveillance) system. Two countries, Bangladesh and Timor-Leste have mentioned that they do not collect data on household contacts in their routine surveillance system. One country (Myanmar) collected this information but had not reported this data for the WHO's Global TB Report 2020 *(1)*.

In 2019, a total of 3.63 million TB patients were notified in these eight SEA Region countries of which 3.37 million (93%) were new and relapse TB patients. Of these new and relapse TB patients, 1.55 million (46%) were 'bacteriologically confirmed'. Of these 1.55 million new and relapse bacteriologically confirmed TB patients notified, it was reported that these patients had ~7.96 million household contacts, of which 4.17 million (52%) were evaluated for TB disease and TBI (**Figure 3**).

All eight countries reported that data on the number of household contacts started on TPT during the year 2019 were available in the routine surveillance system disaggregated by age (less than 5 years, and aged 5 years and above). A total of 176 382 household contacts were initiated on TPT, of which 170 742 (97%) were children aged less than 5 years. Of those initiated on TPT, ~2 845 (1.4%) household contacts (1629 in Bangladesh and 856 in Thailand) were initiated on shorter rifampicin/rifapentine TPT regimens.

The country-wise changes in TPT coverage among household contacts (children aged less than 5 years) of new and relapse bacteriologically confirmed TB patients between 2018 and 2019 are presented in **Figure 4**.

Significant improvement in the coverage in TPT between 2018 and 2019 in children aged less than 5 years is noted in Nepal (from 9% to 36%) and Thailand (from 6% to 58%). The coverage rates remain high and relatively unchanged in DPRK and Timor-Leste between 2018 and 2019. There is a marginal improvement in the coverage in Bangladesh, India, and Myanmar. The TPT coverage at the regional level, among household contacts aged less than 5 years has increased from 26% in 2018 to 33% in 2019.

The TPT coverage among household contacts disaggregated by the age groups (less than 5 years and equal to or more than 5 years) in 2018 and 2019 against the UNHLM targets is presented

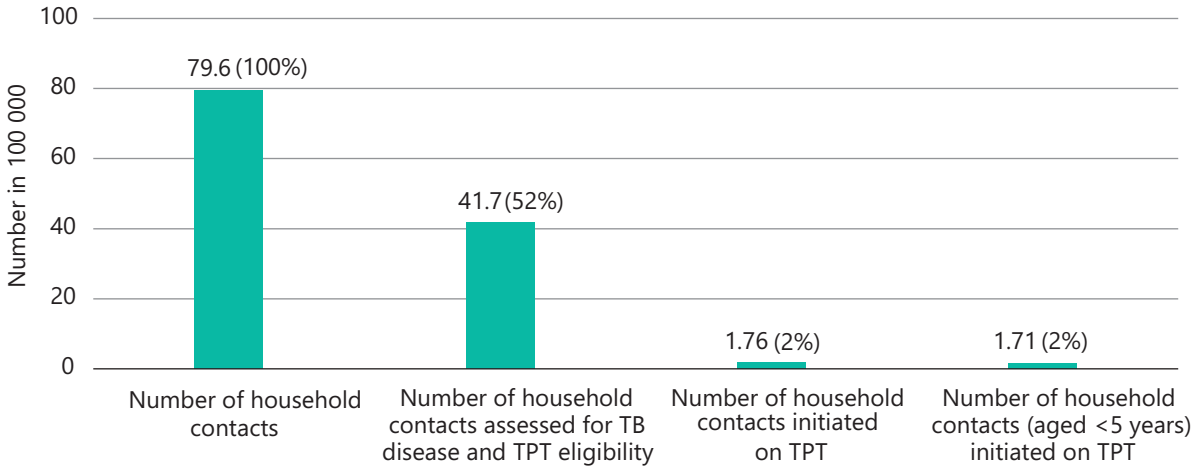
Table 2: Country-wise TPT coverage among household contacts in the eight countries of WHO SEA Region, 2019

	Bangladesh	DPRK	India	Indonesia	Myanmar	Nepal	Thailand	Timor-Leste
General								
Total cases notified	292 942	101 743	2 404 815	568 987	137 325	32 043	89 546	4240
Total new and relapse cases	2 91 595	95 722	2 162 323	562 049	134 501	31 495	87 789	4050
Number of new and relapse pulmonary TB cases bacteriologically confirmed	1 69 049	38 672	966 780	259 956	55 571	18 135	47 301	1734
TB Preventive Therapy								
Data availability on number of household contacts evaluated for TB	No	Yes	Yes	Yes	Yes	Yes	Yes	No
Number of household contacts of bacteriologically confirmed pulmonary new and relapse TB cases notified	NR	123 314	4 957 156	2 694 493	NR	64 715	121 853	NR
The number who were evaluated for Active TB and Latent TB	NR	14 232	3 928 434	79 432	NR	40 222	109 667	NR
Data availability on the number of household contacts of TB cases started on TPT	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Number of household contacts of bacteriologically confirmed pulmonary new and relapse TB cases notified	NR	14 090	109 816	7 641	1 226	2397	10 152	1180
Among those contacts started on TPT, number who were children aged under 5 years	29 880	14 090	109 816	7641	1226	2397	4512	1180
Data on the number of persons treated using shorter TPT regimens	Yes	Not used*	Not used*	Not used*	Not used*	Not used*	Yes	Not used*
Total number of individuals started on shorter	1629	NA	NA	NA	NA	NA	856	NA

Source: Data submitted by SEAR countries for the WHO's Global TB Report 2020 (1); NR= not reported; NA=not applicable

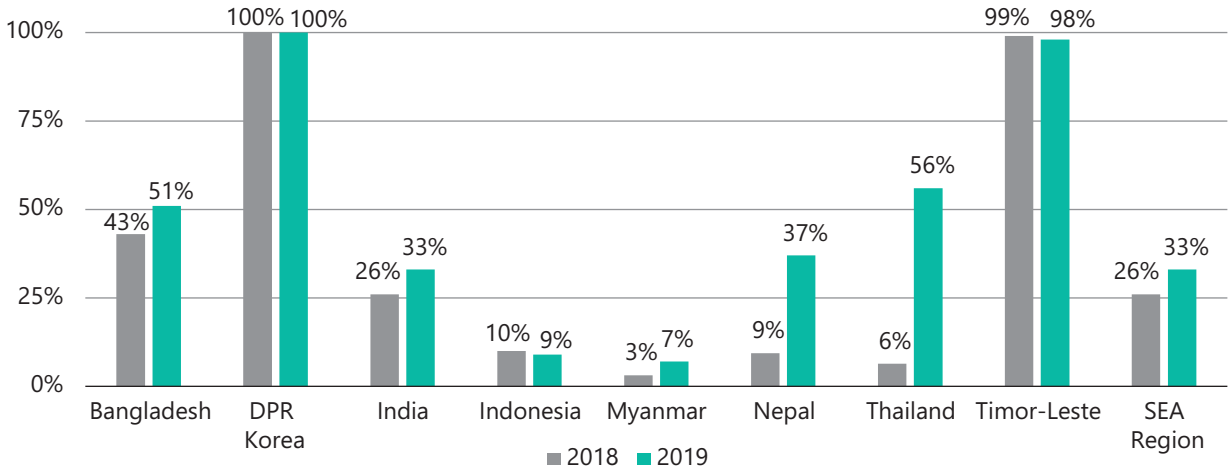
*Not used=shorter TPT regimens were not used in the country during 2019.

Figure 3: Household contact investigation and TPT initiation cascade in eight countries of WHO SEA Region, 2019



Source: Data submitted by the countries for the WHO's Global TB Report 2020 *(1)*

Figure 4: Changes in the TPT coverage among household contacts (aged less than 5 years) of new and relapse bacteriologically positive TB patients in SEA Region between 2018–2019



Source: WHO's Global TB Report 2019 *(13)* and Global TB Report 2020 *(1)*.

In the eight countries, of the 7.96 million household contacts of new and bacteriologically confirmed TB patients, ~4.17 million (52%) were evaluated for TB disease and TPT eligibility, and 1.76 million (2.2%) were initiated on TPT. Nearly 97% of those initiated on TPT were children aged less than 5 years. Of those initiated on TPT, 1.4% were on shorter TPT regimens. Only two countries (Bangladesh and Thailand) reported using shorter TPT regimens.

in **Table 3.** Six out of eight countries have achieved more than 90% of the UNHLM coverage target for 2018 and 2019 for children aged less than 5 years of age - with DPRK and Thailand exceeding the coverage targets. Indonesia and Myanmar have achieved less than 60% of the TPT coverage target. Overall, 89% of the regional target for TPT coverage among household contacts aged less than 5 years has been achieved in these eight countries.

Table 3: Progress towards UNHLM TPT targets among household contacts of SEA Region (2018–19)

Country	Household contacts aged less than 5 years			Household contacts aged 5 years and above		
	RAP Target*	Achieved	% Achieved	RAP Target*	Achieved	% Achieved
Bangladesh	56 542	53 628	95%	54 326	0	0%
DPRK	20 982	24 612	117%	23 668	0	0%
India	213 143	192 925	91%	150 000	0	0%
Indonesia	34 875	15 716	45%	92 000	0	0%
Myanmar	3034	1760	58%	22 000	0	0%
Nepal	3113	3010	97%	8500	0	0%
Thailand	1979	4991	252%	22 000	5837	27%
Timor-Leste	2403	2373	99%	1500	0	0%
Total	336 071	299 015	89%	376 664	5837	2%

*Targets estimated by WHO in consultation with countries of the Region for the period 2018–19

The progress in achieving the TPT targets among household contacts aged 5 years and above is very small (2%) at the regional level with only one country (Thailand) reporting TPT coverage among this age group.

The TPT coverage of new and relapse bacteriologically positive TB patients in the SEAR has increased from 26% in 2018 to 33% in 2019 among household contacts aged less than 5 years. Regarding progress towards UNHLM targets for the years 2018–19, in the eight countries, 89% of the target for TPT coverage among household contacts aged less than 5 years has been achieved but only 2% of the target for TPT coverage has been achieved among household contacts aged 5 years and above.

4.2 STATUS AND PROGRESS IN TPT COVERAGE AMONG PLHIV

Out of the eight countries, one country (DPRK) does not report HIV cases and therefore the data on TPT coverage among PLHIV are not applicable to this country. In the remaining seven countries, the data on TPT coverage on the three indicators are reproduced in **Table 4** to indicate the data gaps for assessing TPT coverage

among PLHIV. Two countries (Bangladesh and Timor-Leste) have not yet reported data on TPT coverage among PLHIV. The remaining five countries (India, Indonesia, Myanmar, Nepal and Thailand) have reported that out of the 297 948 PLHIV newly enrolled for HIV care, 93 996 (32%) received TPT. The percentage of newly diagnosed PLHIV on TPT varied from a low of 0.4% in Thailand to 45% in India. Only three countries, India, Indonesia and Nepal had reported data on the TPT initiation during 2019 among all PLHIV on HIV care in 2019.

Table 4: Country-wise TPT coverage among PLHIV in seven countries* of SEA Region, 2019

TPT coverage indicators in PLHIV	Bangladesh	India	Indonesia	Myanmar	Nepal	Thailand	Timor-Leste
Number started on TPT among those PLHIV newly enrolled for HIV treatment during 2019	NR	77 962/ 174 261	6529/ 53 690	9365/ 35 572	NR	140/ 34 425	NR
Number of PLHIV currently enrolled in HIV treatment who started on TPT during 2019	NR	863 355/ 1 386 581	20 318/ 291 963	NR	2352/ 18 628	NR	NR

Source: Global TB Report 2020 *(1)*

Notes: NR=data not reported.
*In case of DPRK data are not applicable as it does not report HIV infections.

The changes in the TPT initiation rates among PLHIV newly enrolled in HIV care are presented in **Table 5**. Due to non-reporting of data, changes could not be assessed in three (Bangladesh, Nepal and Timor-Leste) out of seven countries that were expected to report on this indicator. In four countries, the TPT coverage rate increased significantly.

Table 5: Country-wise TPT coverage among PLHIV in SEA Region in 2019

Countries	TPT coverage of PLHIV newly enrolled for ART care %	
	2018	2019
Bangladesh	NR	NR
India	17	45
Indonesia	10	12
Myanmar	15	26
Nepal	NR	NR
Thailand	NR	0.4
Timor-Leste	NR	NR
SEAR	15	32

Source: WHO's Global TB Report 2019 (13) and Global TB Report 2020 *(1)*; NR=not reported;

TPT coverage among PLHIV during the first two years against the UNHLM targets is presented in **Table 6.** This target is not applicable to DPRK. In the remaining seven countries, data on TPT coverage are available from five countries for the years 2018 and 2019. In these five countries, the TPT coverage achievement against the UNHLM targets ranges from <1% in Thailand to 830% in India. Overall in these seven countries, 454% of the regional target for TPT coverage among PLHIV has been achieved.

Table 6: Progress towards UNHLM TPT targets among PLHIV in WHO SEA Region 2018–19

Country	TPT coverage among PLHIV		
	Target RAP (2018–19)	Coverage achieved in 2018–19	Coverage %
Bangladesh	1850	NR	NR
India	103 926	863 355	830
Indonesia	55 707	34 084	61
Myanmar	14 304	15 141	106
Nepal	5412	4378	81
Thailand	20 512	140	<1
Timor-Leste	100	NR	NR
Total	201 811	917 098	454

Source: Target estimated by WHO SEARO in consultation with countries of the Region for the period 2018–19; coverage data from WHO's Global TB Report 2019 and 2020. ; NR=not reported

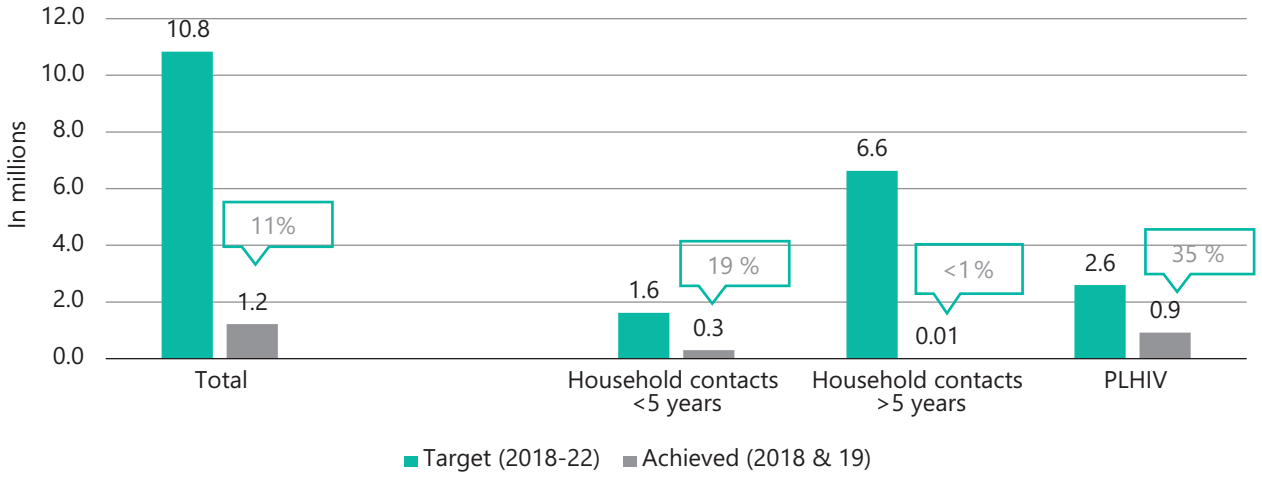
In the SEA Region TPT coverage among PLHIV has doubled from 15% in 2018 to 32% in 2019 due to increased coverage in India and Myanmar. The progress towards achieving the TPT targets as per the UNHLM commitments at the regional level is also on track and exceeds the targets set for 2018 and 2019.

4.3 PROGRESS TOWARDS UNHLM TPT TARGETS FOR 2018–2022

Overall, of the 10.8 million to be provided TPT in the Region (see **Table 1**) between 2018–2022, 1.2 million (11%) have been provided TPT in 2018 and 2019 **(Figure 5)**. The disaggregated coverage against the TPT target for 2018–2022 among household contacts less than 5 years was 19%, among household contacts aged 5 years and above was less than 1% and among PLHIV was 35%.

With the current pace of coverage, TPT targets for PLHIV will be achieved, for household contacts aged less than 5 years may be achieved and will not be achieved for household contacts aged 5 years and above. However, with almost all countries having revised their NSPs and have included TPT in their Global Fund grant

Figure 5: TPT coverage in countries of SEA Region against UNHLM TPT targets for 2018–2022



Source: Data submitted by SEA Region countries for WHO's Global TB Report 2019 and 2020

Overall 1.2 million high-risk individuals (household contacts and PLHIV) have been provided TPT during 2018 and 2019 in SEAR, which accounts for 11% of the UNHLM targets to be achieved by 2022.

applications it is unlikely that the current trends will be followed. Countries may be able to achieve the UNHLM TPT related targets with consistent advocacy, technical and funding support, close monitoring and feedback.

4.4 STATUS OF NATIONAL TPT GUIDELINES IN 2020

In March 2020, WHO released new consolidated guidelines on TPT and an operational handbook on TPT to guide countries to 'how to' implement these guidelines *(6, 14)*. The operational handbook suggests that each country may formulate its own national policy guidelines by adopting and or adapting these global guidelines through a multi-stakeholder consultative process. The national policy guidelines are expected to outline target high-risk groups for TPT within each country context, the mechanisms for assessing the TPT eligibility among the target high-risk groups, TPT regimens to be used, the mechanisms for adherence monitoring, identification and management of adverse drug reactions, the recording, reporting, supervision and monitoring systems.

Seven of the eight countries in this assessment have revised their NSPs in 2020 and have updated their national TPT policies.

Seven out of eight countries for which the information was reviewed, have revised their TPT policies in the year 2020.

4.5 TPT TARGET POPULATIONS

In 2020, seven countries that have revised their NSPs have expanded the target groups for TPT which are mostly in alignment with the latest WHO recommended target high-risk population groups for TPT **(Table 7)**.

Table 7: High-risk groups eligible for TPT in eight countries of SEA Region

High-risk groups recommended by WHO *(14)*	Bangladesh	DPRK	India	Indonesia	Myanmar	Nepal	Timor-Leste	Thailand
PLHIV (without TB)	Yes	NR	Yes	Yes	Yes	Yes	Yes	Yes
Household contacts children less than 5 years of index TB patients	Yes	Yes*	Yes	Yes	Yes	Yes	Yes	Yes
Household contacts children aged more than 5 years, adolescents and adults of index TB patients	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes**
Persons on anti-TNF (tumour necrosis factor) treatment	Yes	No	Yes	Yes	Not yet	Not defined	Not defined	Not yet
Persons receiving dialysis	Yes	No	Yes	Yes	Not yet	Not defined	Not defined	Not yet
Persons preparing for an organ or haematological transplant	Yes	No	Yes	Yes	Not yet	Not defined	Not defined	Not yet
Persons with silicosis	Yes	No	Yes	Yes	Not yet	Not defined	Not defined	Not yet

Source: National strategic/operational plans of countries

Notes: *In DPRK TPT is provided to children 7 years and below.

**In Thailand, the household contacts aged 0–18 years are eligible for TPT and not all household contacts

"Not yet" means that the country has not included these groups for TPT and "not defined" means that the country has mentioned that they will include other clinically vulnerable groups but have not explicitly stated whether these groups are included or not

In all countries given in **Table 7** (except India) the definition of an index case is 'bacteriologically confirmed' pulmonary TB patient. In India, index case is defined as a pulmonary TB patient, both bacteriologically confirmed as well as clinically diagnosed.

Two countries, Indonesia and Thailand, have also included prisoners in the target groups for TPT. Additionally, in Thailand, refugees, migrants, internally displaced populations will also be considered for TPT.

In 2020, seven out of eight countries have expanded the target groups for TPT to cover adolescents and adult household contacts of bacteriologically confirmed TB patients and five countries have included other high-risk clinical groups in to the TPT target population.

4.6 POLICIES FOR ASSESSING TPT ELIGIBILITY IN TARGET POPULATIONS

In all countries, the eligibility for TPT is assessed based on absence of symptoms suggestive of TB disease **(Table 8)**. Chest radiography (to rule out abnormalities suggestive of TB) and positive TBI tests (tuberculin skin test (TST) or interferon-gamma release assay (IGRA)) prior to initiating TPT is recommended only in those places where chest radiography facilities or TBI testing facilities are available. None of the countries in the SEA Region recommend TBI tests for children aged less than 5 years who are household contacts of bacteriologically confirmed TB patients and in PLHIV.

Difficulties in accessing chest radiography or TBI tests are unlikely to be a barrier for TPT scale-up among these populations in SEA Region. TST is used only in Indonesia and Bangladesh. IGRAs are the tests of choice in all other countries. Within the public health system, the TBI tests are available (though not in all public health facilities) in Bangladesh, India, Indonesia and Thailand. Timor-Leste is not planning to use any of the tests for TBI due to operational challenges in implementing these tests.

Table 8: Assessment of eligibility for TPT in high-risk groups in eight countries of SEA Region

Country	To rule out TB		Tests for assessing TBI status	
	Absence of Symptoms	Normal Chest Radiography	TST	IGRA
Bangladesh	Essential	Optional	Optional	Optional
DPRK	Essential	Optional	Optional	Optional
India	Essential	Optional	Will not be used	Optional
Indonesia	Essential	Optional	Optional	Optional
Myanmar	Essential	Optional	Optional	Optional
Nepal	Essential	Not specified*	Not specified*	Not specified*
Thailand	Essential	Optional	Will not be used	Essential**
Timor-Leste	Essential	Optional	Will not be used	Will not be used

Source: National strategic/operational plans of countries

Notes: *Not specified in their latest NSP document

**IGRA test positive result is essential for TPT provision to household contacts aged 5–18 years

An operational research study from Thailand *(15)* assessed the feasibility of improving the process of contact investigation which is important not only from the perspective of identifying TB disease, but also for assessing people for TPT eligibility. The study found that identifying contacts in a person friendly manner, providing contacts with invitation cards and transport costs enhanced their access to TB screening, prevention and treatment. The study also found that contacts living with physical and mental disability and in extreme poverty require additional interventions to assist them in accessing TB screening and care.

Assessment of TPT eligibility in the target groups is as per the latest algorithm suggested by the WHO in almost all the countries. Chest radiography and TBI tests are optional (and not mandatory) in most of the high burden countries. So, availability and accessibility of chest radiography and TBI tests is unlikely to be a major barrier for TPT scale-up in the Region.

4.7 TPT REGIMENS

The TPT regimens recommended in the eight countries of the Region are listed in **Table 9**. Out of the eight TPT regimens recommended for household contacts of drug sensitive bacteriologically positive TB patients and PLHIV in the latest WHO consolidated guidelines on tuberculosis: tuberculosis preventive treatment *(14)*, two regimens (9 H, 36 H) are not recommended by any of the countries in SEA Region. The TPT 6 H regimen is currently used in all countries. The 3 HP regimen is also adopted in all six countries that have updated their NSPs in 2020. The 1 HP regimen is recommended in Indonesia and Thailand, 3 HR regimen is recommended in Indonesia, Thailand and Timor-Leste, and finally the 4 R regimen is recommended only in Indonesia **(Table 9)**. Q-TIB regimen comprising of 6 months of daily isoniazid, pyridoxine and co-trimoxazole (recommended for PLHIV) has not been explicitly listed in any of the NSPs but can be promoted as an alternative to 6 H among PLHIV awaiting availability of shorter rifapentine containing regimen.

In only one country (Indonesia) a Levofloxacin and Ethionamide regimen is recommended for the contacts of DR-TB patients (but not used yet). In all other countries, household contacts of MDR-TB patients are to be closely followed up for the development of TB disease.

Table 9: TPT regimens recommended in high-risk groups in eight countries of SEA Region

Countries	TPT regimen approved (when index case is drug sensitive)								TPT regimens (when index case is DR-TB)
	6 H	9 H	36 H	3 HP	1 HP	3 HR	4 R	Q-TIB	
Bangladesh	Yes			Yes					
DPRK	Yes			No					
India	Yes			Yes		Yes[$]			
Indonesia	Yes			Yes	Yes	Yes	Yes	No	Yes*
Myanmar	Yes			Yes[#]					
Nepal**	Yes			-	-	-	-	-	-
Timor-Leste	Yes			Yes		Yes			
Thailand	Yes			Yes	Yes	Yes			

Source: National strategic/operational plans of countries

Notes: [$] in limited geographies in research mode

*Levofloxacin and Ethionamide

[#]In Myanmar 3 HP will be used 2021 onwards

**Nepal's NSP states that shorter TPT regimens will used in the country but does not specify which regimens.

Seven out of the eight countries have endorsed at least one of the four shorter TPT regimens in their national guidelines, most commonly the rifapentine based 3 HP regimen.

4.8 ADHERENCE AND ADVERSE DRUG EFFECT MONITORING SYSTEMS

TPT adherence mechanisms for household contacts are similar to the systems used for supporting adherence for index TB patients in all eight countries. TPT is either self-administered or caregiver administered (in case of children) and adherence is assessed during routine supervisory visits by healthcare staff using questioning and pill count. The TPT drugs distribution for PLHIV is aligned with that of ART medication refills. None of the countries have proposed financial incentives for TPT completion. India is in advanced stages of using digital adherence technologies such as 99 DOTS and MERM (medication event reminder monitor) to promote adherence to TPT *(16)*.

In all countries specific guidelines for assessing and managing adverse drug reactions to TPT drugs need to be developed.

All countries need to assess if the TPT related adherence and adverse drug effect monitoring and management aspects are adequate and update them (wherever required) to ensure optimal TPT completion rates as TPT is self-administered in almost all the countries.

4.9 TPT RECORDING AND REPORTING SYSTEMS

As indicated earlier **(Table 2)**, in six out of eight countries, contact tracing and TPT provision is captured in their routine TB recording and reporting (surveillance) systems. In Bangladesh, India, Indonesia, Myanmar, and Thailand, TPT related recording and reporting is being integrated into the existing digital platforms. The WHO's Prevent TB application is being used in pilot implementation in one state (Chhattisgarh) in India and being considered in other countries.

The data on TPT provision for PLHIV are recorded in the ART cards, but unlike data on TB disease and TB treatment, the data on TPT provision are not systematically compiled and shared with the NTP on a regular basis. In all countries, the data on TPT provision (especially among PLHIV) appear to be under-reported.

For instance in India, the following components are recorded in the ART records of PLHIV *(17)*. At the time of monthly visit, if the PLHIV is not on isoniazid preventive therapy (IPT), there is a column to record (during routine monthly/ quarterly visits to the ART centres) whether the PLHIV was initiated on IPT during this visit (I) or if IPT is contraindicated (C). If the PLHIV is already on IPT then the following is recorded: IPT stopped due to medical/other reasons or IPT full course completed. This indicates that the data on IPT initiation, contraindication, and completion are recorded and available within the individual PLHIV ART files.

However, while reporting on IPT coverage and completion, the following two numbers are reported in the monthly reports: number of PLHIV newly initiated on IPT during this month and number of PLHIV completed IPT during this month. This does not allow for calculation of proportions or percentages (to assess the completeness and timeliness of IPT initiation among PLHIV and to also ascertain the completion rates) since the report contains only numbers.

It is difficult, therefore, to assess the performance on TPT coverage rates and completion rates without referring to the ART cards. This kind of recording and reporting systems generally result in challenges in reporting on TPT coverage indicator "percent of HIV positive people newly enrolled in care on preventive treatment" – the indicator that is reported to the Global TB Report and generally the reported numbers will be an under estimate of the actual numbers initiated on TPT.

All countries have proposed to adopt the three monitoring indicators (on contact investigation, TPT coverage and TPT completion) recommended in the WHO operational handbook on TPT.

The recording and reporting systems for TPT coverage in other high-risk groups (persons on dialysis, persons on immunosuppressive therapy, persons with silicosis, prisoners) are yet to be developed in all countries of the Region.

TPT related recording and reporting systems are incorporated into the routine TB surveillance systems in almost all countries. There appear to be gaps in the data recorded and reported with respect to completeness and accuracy.

4.10 TPT COVERAGE AND CASCADE OF CARE ANALYSIS

The WHO operational handbook on TPT specifically mentions using 'care cascade' analysis to assess the TPT coverage/uptake/gaps. The five key aspects in the target groups are:

1. Number of persons in TPT target population
2. Of those in target population, the number screened for TB and TPT eligibility
3. Of those assessed for TPT eligibility, the number found to be eligible for TPT
4. Of those eligible, the number initiated on TPT
5. Of those initiated on TPT, the number who completed TPT.

In none of the countries, the data on all five components of the TPT care cascade analysis are routinely available for any of the TPT target groups. Several operational research studies published from the SEA Region countries on the TPT care cascade in the last 10 years show gaps in the TPT coverage and completion rates *(18–23)*.

TPT related care cascade analysis to assess adequacy and completeness of TPT service delivery is not done in any of the countries for any of the target groups.

4.11 COMMUNITY ENGAGEMENT AND DEMAND GENERATION ACTIVITIES

An essential component of TPT implementation is to have explicit plans to engage the community and nongovernmental organisations. Community engagement is critical to improve the reach, acceptability and sustainability of TPT interventions. The End TB Strategy of the WHO has outlined engagement of communities and civil society organisations as one its core components and principles under the "Engage TB approach" *(24)*.

WHO SEARO had engaged members of the TB affected community in the development of the RAP and capacity building on TPT roll out. Several countries in the SEA Region have engaged national and international technical partners in the development of their TPT guidelines and seeking their support for the implementation of TPT at the field level. However, the engagement of members from the TB affected community in the development of national TPT guidelines and/or implementation plans is very minimal at the country level. Almost all countries are planning to enhance the TPT related advocacy, communication and social mobilisation activities in the latest NSPs and have proposed activities on this aspect in their Global Fund applications.

In almost all countries, several national and international technical partners are supporting the respective NTPs in planning and optimal delivery of TPT services. But engagement with TB affected community for TPT scale-up is inadequate at the country level.

4.12 TRAINING OF HEALTH CARE PROVIDERS

Assessing the training needs of various stakeholders (medical officers, peripheral healthcare staff, and programme managers at the subnational levels) for the optimal implementation of the updated TPT guidelines according to their roles and responsibilities is essential to design a training/ capacity building plan. Six countries from the Region propose to undertake these activities within the upcoming Global Fund grants. In almost all countries, currently it is the medical officers at the health facilities who prescribe TPT. It is not clear whether peripheral health workers (as recommended in the WHO operational handbook on TPT) will be empowered to initiate TPT at the field level.

Capacity building of health system staff for optimal delivery of TPT services as per their national guidelines is yet to be completed in all countries.

5. CONSTRAINTS AND OPPORTUNITIES

The major threat to sustain progress and in scaling up TPT in the Region is COVID-19 induced disruptions in TB services. Apart from this, certain other constraints were identified during the qualitative interviews with WHO-CO TB focal persons, which can be broadly classified into six themes. These constraints along with opportunities along with the opportunities to address them are described below.

1. CONSTRAINT: INADEQUATE FOCUS OF NTPs ON TPT IMPLEMENTATION, ITS SUPERVISION AND MONITORING

High TB burden countries in the Region are still focused on early diagnosis and treatment of patients with TB disease (including MDR-TB) and are yet to accord the importance/focus needed for rapid scale-up of TPT. For example, a remark from the India's JMM 2019 Report (page 59) states "low priority given to TPT by national TB and HIV programmes". Issues related to TPT coverage and completion were not part of routine programme review meetings at the national and subnational levels in most of the countries (reflected in JMM reports of Bangladesh, Indonesia, Myanmar and India).

Key informants (from India and Bangladesh) mentioned that improvement in TPT coverage in recent years can be attributed to improvement in the supervision and monitoring of TPT at national and subnational levels and substantial further improvements can be brought about in TPT coverage by improving this component alone.

Opportunities: All countries are in the process of developing the operational guidelines for implementing TPT services as per their latest NSPs. Country specific mechanisms may be outlined within these operational guidelines to ensure that TB programme managers at all levels discuss TPT related aspects in all TB forums. The NTPs should also be encouraged to make use of on-line platforms for organising trainings to promote the uptake and implementation of the latest national TPT guidelines and to identify and address any bottlenecks in TPT implementation.

Operational research studies may be encouraged to identify and address field level implementation challenges in a systematic manner. The WHO recommended structured operational research training initiative (SORT IT) model *(25)* may be adopted to build capacity of TB programme personnel on operational research on TPT. Capacity building of community activists may be undertaken to improve the advocacy on TPT at national and subnational levels.

2. CONSTRAINT: INCOMPLETE AND/ OR INACCURATE DATA ON TPT COVERAGE

The data on TPT coverage are incomplete. This issue is also reflected in the JMM reports of several countries. The following quote from the Bangladesh JMM–2019 provides insights into the issue: "Contact investigation recording and reporting tools are available at health facilities; recording and reporting remains incomplete with sub-optimal monitoring".

The RAP 2019 also states, "The current recording and reporting formats should be amended to include other risk groups, treatment completion rates and other recommended indicators while taking advantage of electronic recording and reporting systems, with their ever-expanding potential in the Region".

Opportunities: In all countries, the recording and reporting system are being reviewed. This opportunity may be used to align the recording and reporting system to capture information on the key components of the TPT care cascade at the national and subnational levels (disaggregated at least by the two high-risk groups – household contacts and PLHIV).

The WHO-HQ has developed a digital platform – Prevent TB – to facilitate monitoring and evaluation of programmatic management of TPT *(26)*. Prevent TB application facilitates the evaluation of contacts for TB disease and TPT eligibility at their residences or in a health facility. It allows monitoring throughout the cascade of preventive care, capturing data at the time of identification of the contact and registration, clinical assessment, screening for active TB, testing for infection and treatment. The platform prompts the health system automatically when there are gaps in this process and generates indicators of performance.

Data validation exercises (as suggested on page 87 in the WHO operational handbook on TPT*(6)*) should be considered in all other countries. This validation exercise includes selecting a random sample of health facilities in the country and assessing TPT coverage and completion by review of records and/or patient interviews.

3. CONSTRAINT: AVAILABILITY AND AFFORDABILITY OF RIFAPENTINE FOR 3 HP REGIMEN

In line with the latest WHO guidelines *(14)*, 3 HP regimen has been endorsed by all six countries who have revised their NSPs in the Region. Almost all countries have highlighted the need to ramp up the production, supply chain of rifapentine and ensure that in-country market price of rifapentine is consistent with the prices quoted in the international market so that countries can easily procure them from their domestic budgets. If the prices can be reduced further, it will become more affordable to the countries.

Opportunities: Close monitoring and advocacy with drug manufactures and procurement and supply agencies to ensure adequate and timely supply of rifapentine regimens can be undertaken. SEA Region include several countries that have drug manufacturers who are part of the global drug supply chains. Advocacy with them may secure availability of drugs in all the countries and ensure that the 'in-country' drug prices do not exceed the prices quoted by the GDF.

4. CONSTRAINT: INADEQUATE COLLABORATION BETWEEN TB AND HIV PROGRAMMES ON THE TPT COMPONENT

The national HIV/AIDS programmes have taken up the onus of implementing TPT among PLHIV and have integrated TPT services within the ART services in all countries of SEA Region. The focus of the ART programmes is still on early diagnosis and treatment of TB among PLHIV. In some countries (specifically in Indonesia,

Bangladesh, and Thailand), the clinicians involved in the provision of ART are concerned with the consequences of providing TPT to PLHIV who may have undiagnosed TB. This is, a major barrier for TPT provision to PLHIV.

In addition, the data on TPT coverage and completion are not routinely communicated between HIV and TB programmes. This is also reflected in the lack of data on TPT coverage among PLHIV from three of the seven countries **(Tables 2 and 5)**. Apart from this, a few countries have also reported issues with procurement and supply of appropriate TPT regimens including pyridoxine (e.g. India JMM Report, 2019).

Opportunities: Online platforms may be used to organise joint webinars or sensitisation meetings between the NTP's and the national HIV programme staff to discuss and sensitise them on the latest TPT guidelines. This opportunity may also be used to update the national ART guidelines as several countries are in the process of drafting the latest operational guidelines on TPT. ART recording and reporting systems may be revised to incorporate recording and routine reporting on TPT coverage and completion among PLHIV.

Discussion on TPT coverage and completion should be made a part of the agenda of the monthly or quarterly TB-HIV collaboration meetings that are held in almost all countries. Issues related to drug procurement and supply (if any) may be sorted out on priority.

5. CONSTRAINT: INADEQUATE TRAINING OF HEALTHCARE PERSONNEL (INCLUDING DOCTORS AND PERIPHERAL HEALTH STAFF) ON THE LATEST TPT GUIDELINES

All countries of the SEA Region are yet to undertake assessment of training needs of health personnel on TPT, develop capacity building tools, design and implement appropriate capacity building curricula in their respective countries. As a result, healthcare staff are unaware of the latest TPT guidelines and their roles and responsibilities in implementing the latest guidelines.

Opportunities: Tools and resources for technical assistance to NTPs of all countries in order to assess the training needs, and support development of context specific tools and curricula have been developed. These are available at regional and global level and should be used.

WHO-HQ is in the process of developing e-learning modules on TPT. These modules are likely to be available by the end of the year 2020 or early 2021. WHO SEARO has developed a workbook – WHO operational handbook on TPT. These training tools can be adopted and adapted by the countries to reduce the time and cost involved in developing the training tools.

6. CONSTRAINT: INADEQUATE COMMUNICATION AND SOCIAL MOBILISATION ACTIVITIES TO GENERATE OR IMPROVE DEMAND FOR TPT FROM THE COMMUNITY

A few countries (Indonesia, Myanmar and Bangladesh) in the Region have indicated that the poor demand and acceptability of TPT among the community is one of the major barriers for improving TPT coverage in the countries. A couple of countries have also suggested the need for support from technical experts to design, plan and implement context specific communication and social mobilisation activities to improve TPT coverage.

The RAP also states that the "Demand for TPT at the community level needs to be generated by disseminating appropriate knowledge and evidence on the benefits of preventive treatment. Community engagement has been increasing in the Region, and communities can become allies in this endeavour".

Opportunities: Several nongovernment organisations, community based organisations, and partners are supporting the implementation of various TB services in the SEA Region countries *(27)*. They can become partners in facilitating demand generation for TPT services from the community. Similarly several communication and social mobilisation tools and examples that are being used in other areas of TB care *(24)* can be adapted to improve the demand and acceptability of TPT services.

6. CONCLUSIONS

There has been considerable progress on improving TPT coverage among household contacts (aged less than 5 years) and PLHIV in the SEA Region in 2019. However, the progress in providing TPT to household contacts aged 5 years and above lags.

In 2020, several countries in the SEA Region have revised and aligned their national TPT policies with the latest WHO TPT guidelines. This includes expanding the TPT target population to include all household contacts, aligning the algorithms for assessing TPT eligibility and adopting the shorter TPT regimens.

Major challenges for TPT scale-up include: inadequate priority given to the TPT by the NTPs, deficiencies in recording and reporting of information on TPT implementation, non-availability of adequate quantities of rifapentine, lack of context specific training tools and advocacy, communication and social mobilisations plans to address bottlenecks in demand and supply of TPT services. However, there are many opportunities not just in newer and more affordable drugs and diagnostics, but also for integrating TPT into existing HIV and TB programming. These must be leveraged and used at scale to ensure that the Region is able to bring down TB incidence faster and prevent needless suffering caused by TB in people where it can be prevented.

7. RECOMMENDATIONS

Recommendations for improving TPT scale-up in the countries of the SEA Region include advocacy and technical support to the NTPs on the following aspects. Specifically, it is critical to:

- Ensure that adequate importance is given to TPT implementation by NTPs and allocation of necessary resources
- Adopt "cascade of care analysis" as a means for improving TPT coverage in the target populations by aligning the recording, reporting, supportive supervision and monitoring systems
- Encourage operational/implementation research to identify and address gaps in the cascade of TPT care
- Ensure availability of adequate quantities of rifapentine through appropriate quantification
- Advocate with drug manufacturers for price reduction
- Develop tools for training and sensitisation of all categories of health personnel on the latest national and international TPT guidelines, and for the development of TPT related national advocacy, communication and social mobilisation plans to increase demand for TPT.

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ANNEXURES

ANNEXURE 1: CHECKLIST

Checklist for conducting desk review on TPT for the situational analysis

Aspects to be covered in the situational analysis report for each country

- NTP policy for TPT in terms of
  - → target groups for TPT, algorithms for assessing eligibility (including role of chest radiography and assessing tests for TBI) and TPT regimens (including transition)
  - → the readiness of countries to use and scale-up rifapentine (registration, mechanisms to import it, strategies to replace any existing IPT with P containing regimens, including 1 HP, use of 3 HP in children more than 2 years, training/implementation documents)
  - → possibilities to introduce or expand TPT for MDR-TB
  - → opportunities to insert the PREVENT TB app or equivalent into the suite of digital tools for management of data for TB or HIV control
  - → compare the NTP TPT policy with the latest WHO TPT guidelines.
- Status of formulating action plans/ operational guidelines for implementing TPT and description of the following key elements as per these plans/guidelines
  - → National and subnational targets (NSP) for TPT as compared to projected targets for achieving UNHLM commitments
  - → What LTBI diagnostics are being used and what are the proposed diagnostic tests to be used
- Capacity for TST and/or lab network for TPT related diagnostics (IGRA testing) and quality assurance mechanisms
  - → Human resource for TPT, who are doing it? Are they trained? Any new HR or is the routine staff expected to do the activities?
  - → Adherence monitoring systems/ technologies used; are digital tools used for adherence monitoring for TB treatment?
  - → Mechanism for drug logistics management (including supply for HIV settings)
  - → Roles and responsibilities of various stakeholders (including mechanisms for community participation in TB screening, referral, TPT start and TPT continuation)
  - → Recording, reporting, supervision and monitoring systems (are digital tools used? Scope for WHO PREVENT TB app)
  - → Systems for operational research on TPT
  - → Plans for transition to new regimen in terms of policy, new regimen and target groups
  - → Basis of costing and availability of funding.
- Availability of training materials for implementation of TPT (existing and new ones) and status of training of key stakeholders (NTP staff) on TPT implementation

- To describe the TPT coverage through cascade of care analysis for the year 2019
  - → Numbers of persons in the TPT target population (as per the national policies)
  - → Of those in the target population, the number (and proportion) screened for TPT eligibility and the number (and proportion) found to be eligible for TPT
  - → Of those eligible, the number (and proportion) initiated on TPT and of those initiated, the number and proportion completed TPT.
- Challenges for implementing national TPT management guidelines and key recommendations to address the challenges, gaps in TPT implementation
- Any success stories

ANNEXURE 2: LIST OF DOCUMENTS REVIEWED FOR THE DESK REVIEW

1. Bangladesh: National Strategic Plan (2020), Global Fund Application (2020) and draft of the latest Joint Monitoring Mission report (2019), Data submitted to the Global TB Report, 2019 and Global TB Report, 2020.
2. Bhutan: Data submitted to the Global TB Report, 2019 and Global TB Report, 2020.
3. DP: Joint Monitoring Mission (2017), Data submitted to the Global TB Report, 2019 and Global TB Report, 2020.
4. India: National Strategic Plan (2017 version and the latest draft of 2020 version), Draft LTBI technical and operational guidelines (2020), Data submitted to the Global TB Report, 2019 and Global TB Report, 2020.
5. Indonesia: National Strategic Plan (2020), Global Fund Application (2020) and draft of the latest Joint Monitoring Mission report (2019), Data submitted to the Global TB Report, 2019 and Global TB Report, 2020.
6. Maldives: Data submitted to the Global TB Report, 2019 and Global TB Report, 2020.
7. Myanmar: National Strategic Plan (2020), Global Fund Application (2020) and draft of the latest Joint Monitoring Mission report (2019), Data submitted to the Global TB Report, 2019 and Global TB Report, 2020.
8. Nepal: JMM Report 2019, Data submitted to the Global TB Report, 2019 and Global TB Report, 2020.
9. Sri Lanka: Data submitted to the Global TB Report, 2019 and Global TB Report, 2020.
10. Thailand: Draft of the National Strategic Plan (2020) and Global Fund Application (2020), Data submitted to the Global TB Report, 2019 and Global TB Report, 2020.
11. Timor-Leste: National Strategic Plan and TB guidelines (2020), Global Fund Application (2020), Data submitted to the Global TB Report, 2020.

ANNEXURE 3: GENERIC INTERVIEW GUIDE

Interview guide (Generic)

Dear XXXX

My name is YYYY. I am engaged by WHO SEARO as a technical consultant to prepare a report on the status of TPT implementation in the SEA Region in the context of the UNHLM in September 2018 and adoption of RAP on programmatic management of latent TB. I am gathering the required information for this status from the NSPs, Global Fund application, latest joint monitoring mission reports, Global TB Report, national TPT action plans and by interacting with the key stakeholders (WHO-CO) TB focal persons, NTP focal persons and any other stakeholders involved in TPT implementation in the country).

Please find attached the data that are collected from various existing documents for XXX (country). Please allow me to take you through the data during our call. I will need some more information on the following issues (listed below) during our call. The purpose of this call is to get your inputs. If you do not have your inputs to any of these questions at this stage, but would like to share them later or if you want to change your inputs that you have given now later, please feel free do so. Before finalising my LTBI Report to WHO SEARO, I will share the draft report with all the respondents for your final review. The interview may take about 45 minutes. If you are constrained by time, we can have multiple sessions as per your convenience.

MAJOR ISSUES

1. Has the NTP drafted any newer national action plan/guidelines to enhance TPT implementation in the country following the UNHLM in September 2018? If yes, can you please share that with WHO SEARO?
2. Are there any issues with regulatory approvals for using shorter rifapentine based TPT regimens (3 HP or 1 HP)?

   (Probing questions: Is rifapentine registered/ approved for use in the country? When is the rollout of shorter rifapentine regimens expected? Who/which national programme is responsible for procurement of TPT drugs?)
3. What algorithm is being used to assess TPT eligibility? (optional)
   a. Is chest radiography essential to rule out TB in asymptomatic PLHIV and household contacts?
   b. Is positive LTBI tests (TST/IGRA) essential to provide TPT?
      i. At what level of the health system is TST available?
      ii. At what level of the health system is IGRA available?
      iii. Is availability of tests a bottleneck for TPT expansion in the country?
4. What are the issues/bottlenecks for improving TPT coverage among PLHIV and household contacts (less than 5 years) and are they resolved? How are they resolved?

5. Recording and reporting systems for TPT management:
    a. Is recording and reporting for TPT data variables, paper based or electronic?
    b. Are they integrated into TB recording and reporting system; is there any plan to move to digital tools for data capture and reporting (e.g. WHO PREVENT-TB app)?
    c. What indicators are used to monitor TPT coverage at the national level?
    d. Are other clinical risk groups receiving TPT captured?
6. Are there any mechanisms for monitoring adverse drug reactions due to TPT? If yes, can you explain a bit more on it?
7. Are there any major researches being done to improve TPT coverage in the country? If yes, what are these research studies, who are doing them and the timeframe for completion of these studies?
8. Are there any areas where external support from WHO SEARO or WHO-HQ is needed for TPT scale-up in the country?
9. Any success stories that can be highlighted at the national and international level?
    a. Capacity for TST
    b. Laboratory capacity to take up IGRA testing if resources become available
    c. Household contact investigation could also be a specific question – strengths, weaknesses, plan

MINOR ISSUES

1. Need some clarity on definitions used for index case, household contact being used in the country
2. What are the reasons for non-inclusion of the following high-risk groups for TPT in the country?
    a. Children more than 5 years, adolescents, and adult household contacts
    b. Patients on anti-TNF treatment
    c. Patients receiving dialysis
    d. Patients preparing for an organ or haematological transplant
    e. Persons with silicosis
    f. When are the above-mentioned target populations (a-e) planned to be included for programmatic management as per NSP or national guidelines?
3. Any other high-risk groups being considered for inclusion in TPT coverage? If yes, who are they?
4. Are there any TPT training materials for peripheral staff?
5. What are the TPT adherence monitoring systems for patients? (self-administered, video assisted, directly observed)
6. Community engagement for TPT rollout: How is this happening?
7. Are TPT related messages being communicated along with other TB related messages in mass media to popularise TPT?
8. Who are the stakeholders involved in promotion of TPT in the country?
9. Are there any efforts to engage the private sector for TPT provision?
    a. Are there experiences of TPT use in private sector – publications etc.
    b. Also, it may be important to assess capacity in private sector to undertake IGRA

ANNEXURE 4: MISCELLANEOUS

COMPARISON OF COUNTRY TPT GUIDANCE TARGETS PROVIDED BY WHO SEARO AND STOP TB PARTNERSHIP (2018–2022)

Stop TB partnership has also estimated TPT targets to guide countries towards UNHLM TPT targets for the period 2018–2022. At the Regional level, there is not much difference between the target guidance provided by the RAP and the Stop TB Partnership. However, at the individual country level, there are huge differences. These differences are highlighted in this Annexure in the following table.

Country	TPT targets by WHO SEARO (2018–22)	TPT targets provided by the Stop TB Partnership (2018–22)	Absolute difference*	Percentage difference*
Bangladesh	856 732	963 560	(106 828)	-12%
Bhutan	2695	2550	145	5%
DPRK	314 013	256 130	57 883	18%
India	6 034 062	6 866 100	(832 038)	-14%
Indonesia	2 318 484	1 619 480	699 004	30%
Maldives	496	552	(56)	-11%
Myanmar	532 200	435 840	96 360	18%
Nepal	108 202	94 190	14 012	13%
Sri Lanka	33 156	35 620	(2464)	-7%
Thailand	616 613	319 620	296 993	48%
Timor-Leste	18 030	18 210	(180)	-1%
Total	**10 834 683**	**10 611 852**	**222 831**	**2%**

*Number in brackets or percentages in negative sign indicate that the Stop TB Partnership targets exceed those derived by the WHO SEARO in consultation with countries.

The methodology adopted by WHO SEARO considers country-specific information on the household contacts, proportion of under-5 population using country-specific population structure, projected country-specific incidence of TB and PLHIV. The WHO SEARO estimates also takes into consideration the pace of TPT scale-up expected to happen during this time frame.

TB preventive treatment (TPT) is essential to reduce the incidence of TB disease among highrisk individuals. TPT is a critical public health intervention to eliminate TB disease in the WHO South-East Asia Region. In September 2018, at the first-ever United Nations High-Level Meeting on TB, Heads of State from across the world pledged to provide TPT to at least 30 million people at risk of the disease globally between 2018 and 2022. At the regional level, this translates to delivering TPT to at least 10.8 million high-risk individuals.

In 2020, the WHO Regional Office for South-East Asia conducted a situational analysis to assess the progress made in the adoption and implementation of latest TPT policies by Member States of the Region. This report contains the details of this situational analysis. The analysis suggests that despite considerable progress the achievements in TPT coverage among high-risk groups are below the desired levels. At the current pace of scale-up) the Region is unlikely to achieve the regional TPT targets by 2022. Focused attention and coordinated action are needed from all stakeholders to achieve rapid scale-up of TPT services in the South-East Asia Region.

World Health Organization
REGIONAL OFFICE FOR South-East Asia

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