

Urgent need to address the slow scale-up of TB preventive treatment in the WHO South-East Asia Region

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SUMMARY

In September 2018, all countries made a commitment at the first ever United Nations High-Level Meeting (UNHLM) on TB, to provide TB preventive treatment (TPT) to at least 30 million people at high-risk of TB disease between 2018 and 2022. In the WHO South-East Asia Region (SEA Region), which accounts for 44% of the global TB burden, only 1.2 million high-risk individuals (household contacts and people living with HIV) were provided TPT (11% of the 10.8 million regional UNHLM TPT target) in 2018 and 2019. By 2020, almost all 11 countries of the SEA Region had revised their policies on TPT target groups and criteria to assess TPT eligibility, and had adopted at least one

shorter TPT regimen recommended in the latest WHO TPT guidelines. The major challenges for TPT scale-up in the SEA Region are resource shortages, knowledge and service delivery/uptake gaps among providers and service recipients, and the lack of adequate quantities of rifapentine for use in shorter TPT regimens. There are several regional opportunities to address these gaps and countries of the SEA Region must make use of these opportunities to scale up TPT services rapidly to reduce the TB burden in the SEA Region.

KEY WORDS: TB preventive treatment; coverage; uptake; South-East Asia Region; challenges; opportunities

Of the six WHO Regions, the South-East Asia Region (henceforth, ‘the Region’) has the highest TB incidence. In 2019, about 4.3 million persons developed TB disease (44% of the global incidence) in the Region and more than 650 000 persons died due to the disease (46% of the global TB deaths). Only 78% of the estimated incident TB persons were notified by the national TB programmes (NTPs) in the Region, the remainder being ‘missed’ by the health systems.¹ There are huge variations in the TB burden in the countries of the Region both in terms of absolute number of TB patients and as well as in the annual incidence rates. Six out of the 11 countries (Bangladesh, Democratic Republic of Korea, India, Indonesia, Myanmar and Thailand) of the Region are ranked among the 30 high TB burden countries in the world. It is estimated that 30% of the population in the Region is infected with TB and 1.2% (95% confidence interval [CI] 0.9–1.6) of the population is recently infected and at high risk of progression from infection to disease.²

All the countries in the Region have committed to achieving the United Nations Sustainable Development Goals (SDGs) target of ending the TB epidemic by 2030 through the implementation of the WHO End TB Strategy.³ This entails an 80% reduction in

the TB incidence rate from 238 patients per 100,000 population in 2015 to 48 per 100,000 population in 2030, a 90% reduction in the number of TB deaths from nearly 725,000 in 2015 to less than 72,500 deaths in 2030.

These reductions in incidence cannot be achieved by treating those with TB disease alone. Recent epidemiological data indicate that TB disease prevention is essential if the SDG targets in the Region are to be met. Optimal implementation of TB preventive treatment (TPT) alone in certain high-risk groups such as household contacts and people living with HIV (PLHIV) has the potential to reduce the annual TB incidence rates by 8.3% (95% credible interval [CrI] 6.5–10.8) relative to 2015, in the absence of any additional interventions.^{4,5}

To note, prevention is always better than cure, and no person in whom TB disease can be averted should be allowed to suffer when the tools to prevent suffering are available. Preventing TB has dual benefits. It prevents morbidity and mortality at the individual level, and reduces the TB burden by curtailing its transmission from individuals who would otherwise develop TB.⁶ Furthermore, preventing TB also mitigates the disproportionate suffering that TB patients and their families would experience whenever there is

stress on the health system, as shown by the present COVID-19 pandemic.^{7–9}

TPT is a critical component of good TB care—no child under the age of 5 years of a parent or a household member who has been detected with TB should be left without TPT, just as no person with compromised immunity should be left unprotected to the higher risk of progressing to disease. TPT reduces the risk of progression from TB infection to TB disease by about 60%, but can be as high as 90% among certain high-risk groups (such as PLHIV).^{10,11} Systematic TPT is currently recommended by WHO for household contacts of bacteriologically confirmed pulmonary TB patients, PLHIV, those with silicosis, those receiving dialysis or anti-tumour necrosis factor treatment, or individuals preparing for haematological or organ transplantation. Depending upon the country context, people with risk factors other than those mentioned above (such as prison inmates, non-household close contacts, people with diabetes) can also be considered for systematic screening and TPT.⁶ With the discovery of newer, shorter and less toxic regimens, TPT has become more acceptable for the beneficiaries and is feasible for NTPs to provide TPT to high-risk groups on a large scale.⁶

At the regional level, the numbers of individuals at high risk of TB disease that need preventive treatment to avert one TB case is 64 (95% CrI 55–74),⁵ which is a highly attractive public health proposition. In line with the commitments made by the countries during the 2018 UNHLM on TB, at least 10.8 million high-risk persons need TPT between 2018 and 2022 in the Region.¹²

The risk of progression from TB infection to disease is not uniform and is highest in those who are recently infected with TB and in those whose immunity is compromised.¹³ Targeted TPT provision to high-risk individuals (without TB disease)—in contrast to population-wide use of TPT—is recommended based on the need to balance potential benefit with risk from medication.¹⁴ Furthermore, studies suggest that integrating TPT services into a comprehensive strategy that implements quality services for active case finding and treatment, strengthening linkages to HIV and child services will be more cost-effective in accelerating progress towards TB elimination as opposed to implementing it as a stand-alone public health intervention.^{15,16}

In this paper, we assess the progress made by the countries in the Region in scaling TPT coverage in 2018 and 2019 and take stock of achievements against UNHLM commitments. Apart from service coverage, we also review major changes made by these countries in TPT-related policies, while highlighting challenges and opportunities for TPT scale-up. This assessment was based on a review of data reported by Ministries of Health to the Global TB Programme and was supplemented by key informant

interviews in WHO country offices and community representatives.¹⁷

PROGRESS ON TPT PROVISION IN SOUTH-EAST ASIA REGION COUNTRIES

During 2018 and 2019, a total of 1.2 million high-risk individuals (0.3 million household contacts of all ages and 0.9 million PLHIV) were initiated on TPT. This constitutes 11% of the UNHLM TPT target to be achieved by 2022 (Figure 1). TPT was provided mostly to PLHIV and children aged <5 years who were household contacts of bacteriologically confirmed pulmonary TB patients. TPT coverage among household contacts aged ≥5 years was less than 1% of the target, mainly because most countries did not have a policy for providing TPT to household contacts aged ≥5 years during these 2 years. At the current pace of implementation, the UNHLM TPT target for household contacts is unlikely to be achieved by 2022 in the Region. The TPT coverage among household contacts aged <5 years and PLHIV varies hugely across the SEAR countries, although in most countries, there has been improvement in TPT coverage in 2019 compared to 2018 (Figure 2A and Figure 2B). In 2019, the TPT coverage among household contacts aged <5 years in the Region is identical to the global average (33%), but the TPT coverage among PLHIV in the Region lags behind the global average (32% vs. 50%).¹

In 2020, the NTPs of seven of the 11 countries of the region (Bangladesh, India, Indonesia, Myanmar, Nepal, Thailand and Timor-Leste) revised their national strategic plans and updated their TPT policies. All seven countries have expanded the target groups for TPT to cover individuals aged ≥5 years who were household contacts of bacteriologically confirmed TB patients. Five countries have also included other high-risk clinical groups recommended by the WHO in their TPT target population. In most countries, the assessment for TPT eligibility in the target groups is aligned with the algorithm suggested in the latest WHO guidelines on TPT.⁶ Chest radiography (to rule out TB disease) and TB infection tests (tuberculin skin tests and interferon-gamma release assays) to identify those with TB infection are optional. Therefore, the unavailability of chest radiography and TB infection tests do not need to be barriers.¹⁸ However, the success of this approach is dependent on good TB symptom screening practices to prevent people with TB disease being incorrectly prescribed TPT and improved access to rapid molecular diagnostic testing (such as Xpert[®] MTB/Rif assay, Cepheid, Sunnyvale, CA, USA); digital chest radiography diagnostic services are also expected to minimise incorrect TPT prescription. Almost all countries have now incorporated at least one of the four shorter TPT regimens into their

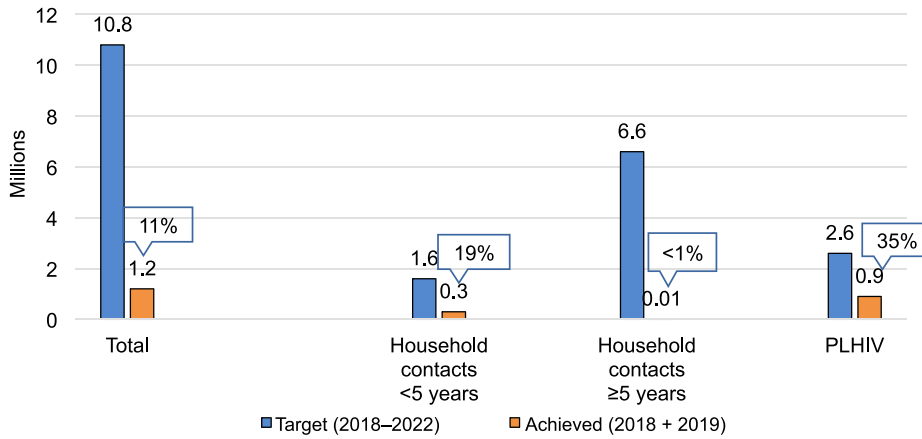


Figure 1 TPT coverage in countries of the SEAR assessed against UNHLM TPT targets for 2018–2022. Source: Data submitted by all 11 SEAR countries for the WHO Global TB report, 2019³⁵ and Global TB report, 2020.¹ TPT = TB preventive treatment; SEAR = South-East Asia Region; UNHLM = United Nations High-Level Meeting.

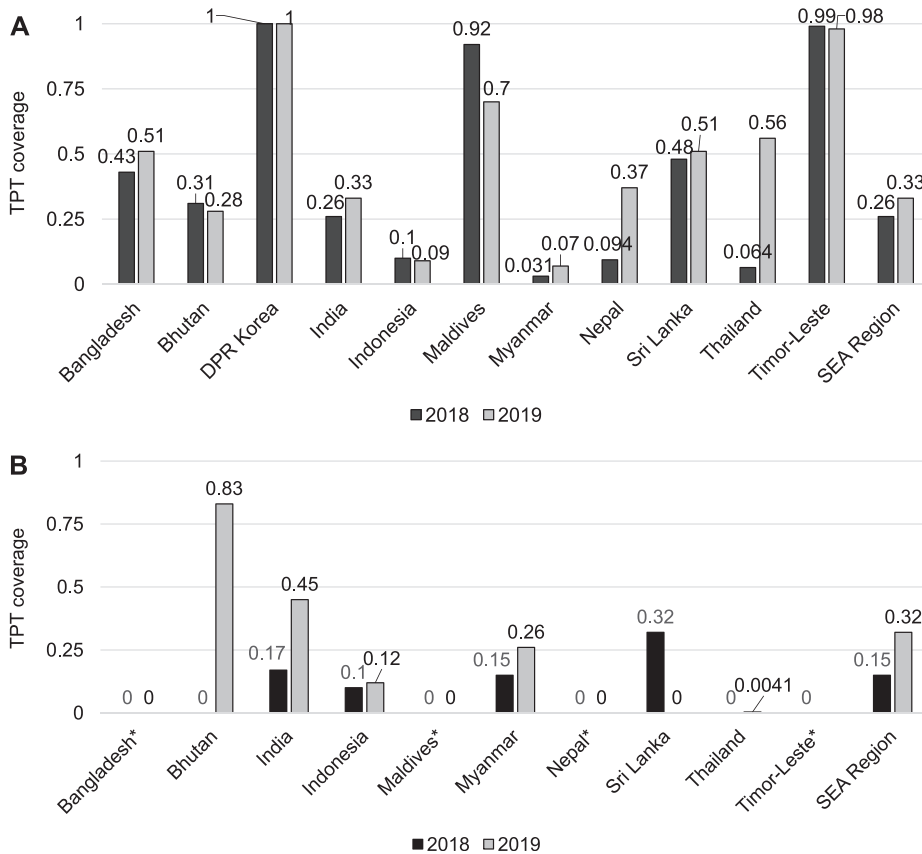


Figure 2 **A)** TPT coverage among household contacts aged <5 years of bacteriologically confirmed TB patients in the WHO SEA Region, 2018–2019. Source: WHO Global TB report, 2019³⁵ and Global TB report, 2020.¹ **B)** TPT coverage among people living with HIV in the WHO SEA Region, 2018–2019. Source: WHO Global TB report, 2019³⁵ and Global TB report, 2020.¹ *Bangladesh, Maldives, Nepal and Timor-Leste have not reported data on this indicator for 2018 and 2019; Bhutan and Thailand have not reported on this indicator for 2018 and Sri Lanka has not reported on this indicator for 2019. DPR Korea does not report having people living with HIV and therefore this indicator is not applicable to that country. Regional coverage consists of data from only those countries which reported on this indicator. DPR = Democratic People’s Republic; SEA = South-East Asia

national guidelines, most commonly the 3-month weekly rifapentine (RPT) and isoniazid (3HP) regimen.

There has been limited progress on certain aspects. TPT is self-administered, and the NTPs of almost all countries are yet to review whether these are adequate and strengthen (if required) the adherence and adverse drug reaction monitoring and management systems. There appears to be gaps in TPT data recording and reporting in terms of completeness and accuracy. Except for a couple of countries (India and Thailand), the progress in revising the recording and reporting systems has been slow. In all countries, TPT care cascade analysis is not done routinely to assess the adequacy of TPT uptake and completion in target groups. Capacity building of health system staff for optimal delivery of TPT services as per their respective national guidelines is yet to be completed in all countries.

Several national and international technical partners are involved in supporting the NTPs in planning and delivery of TPT services in all countries. However, private sector engagement in the provision of TPT services is very minimal, even in those countries of the Region where it plays a significant role in TB services provision (Bangladesh, India, Indonesia, Myanmar and Nepal). Similarly, engagement with the TB-affected community for TPT scale-up is inadequate at the country level, and there have been very limited efforts made by the NTPs to inform and educate the community about the benefits of TPT.

CHALLENGES FOR TPT SCALE-UP

The several challenges for TPT scale-up in the Region can be viewed at a supply and demand level and spread across both policy and implementation areas. The current major challenges for TPT scale-up are as follows:

Resources

Although all the countries have adopted the latest policies for TPT, the scale-up will require additional financial and human resources (for which a costing exercise is being undertaken by WHO SEAR Office).¹⁹ The NTPs of all high-burden countries in the Region are underfunded, and the COVID-19 pandemic has put additional strain on health systems and on resources. Ensuring the allocation of adequate resources to match the scale-up plan will therefore be one of the major challenges for all high TB burden countries in the Region. Unless policy makers see TPT as a priority public health intervention to reduce the TB burden under all circumstances, TPT scale-up may not happen at a pace necessary for ending TB in the Region.

Inadequate knowledge about TPT among service providers and service recipients

There is still a strong perception among many policy makers, programme managers and health care providers that TB diagnosis and treatment is more important than TPT, that TPT may worsen drug resistance, that TPT-related drug interactions and drug toxicities are difficult to manage and that drug risks may outweigh the perceived benefits. These misconceptions play a significant role in delaying the scale-up of services, and also in sub-optimal provision of TPT services to PLHIV and household contacts. Studies from the Region show that feeling healthy, stigma, poor awareness are barriers for contact screening and TPT uptake among household contacts.^{20,21}

Availability and affordability of rifapentine in shorter newer TPT regimens

According to the latest WHO guidelines on TPT,⁶ the shorter weekly RPT plus isoniazid regimen has been adopted by almost all countries in SEAR due its smaller number of doses, similar effectiveness, and the perceived operational possibility of handling drug logistics and monitoring the provision of this regimen on a large scale without overwhelming the existing health system capacity. However, there is a global shortage of RPT due to inadequate production and the high drug price of this regimen (~US\$ 15 per person for a full course of 12 doses of RPT and isoniazid (3 HP regimen) for a person weighing ≥ 50 kg²²) is unaffordable in several countries in the Region. This is one of the challenges that needs to be addressed at the global level to enable TPT scale-up in the Region.

Disruptions due to COVID-19

Finally, the disruptions due to the COVID-19 pandemic have had a profound effect on the TB services in the Region. Several countries have witnessed up to a 30% decline in the TB case notification in the first 6 months of 2020.¹ This reduction affects 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 confirmed pulmonary TB patients detected).

OPPORTUNITIES FOR TPT SCALE-UP

TPT is a potent public health intervention to reduce the TB disease burden in the SEAR,^{10,23,24} and TPT services should not be neglected or side-lined. TPT scale up can be used as an opportunity to minimise the collateral damage of COVID-19 pandemic on TB disease burden in SEAR. Policymakers, and national and international funding agencies should therefore

exploit potential synergies and allocate necessary financial resources for TPT scale-up by. All countries are in the process of strengthening contact investigation of index cases to enhance TB case-finding activities. This also helps in identifying people at risk for developing the disease, i.e., those in need of TPT. Embedding TPT services in all case-finding activities may help in minimising the cost of reaching out to these populations and maximising the benefits. Also, all countries are in the process of formulating or strengthening the existing social health insurance/protection schemes in order to achieve universal health coverage as part of the SDG-3. TPT can become an integral part of these social health insurance/protection schemes (for example, conditional cash transfers) to prevent TB disease among high-risk individuals^{25,26} and this will contribute towards SDG-1, as well of ending poverty.

The NTPs of all SEAR countries have made ambitious national strategic plans to scale up TPT services, and are currently in the process of revising their technical and operational guidelines, recording, reporting, training, supervision and monitoring systems as per their latest TPT policies. The latest WHO operational handbook on TPT provides guidance for addressing all the major technical and operational concerns of programme managers, medical officers and health care workers at the field level;^{6,16} however, countries need to adapt this guidance and develop their own technical and operational guidelines. Care must be taken to ensure that the TPT services are decentralised, community-based and ‘person-centric’. In 2021, the WHO will release new e-learning tools and training modules on TPT for health care providers who are at the forefront of service delivery as part of a knowledge-sharing platform, alongside other online resources from partners.^{27,28}

The WHO has also co-developed the Prevent TB mobile application to strengthen recording, reporting and monitoring systems to enable care cascade analysis.²⁹ Countries may adapt such tools for strengthening the monitoring of TPT services and integrate them with other preventive efforts (e.g., TB screening). Operational research studies may be undertaken to quickly identify and address field-level implementation challenges and to pin down the most cost-effective and feasible context-specific strategies for rapid scale-up of TPT services in the Region.³⁰ Operational research may also quantify the burden of the problem among high-risk populations at national and sub-national level. In addition, there is also a need to exploit better the existing regional/country platforms to disseminate knowledge and facilitate cross learnings.

All stakeholders should appeal to drug manufacturers and drug procurement and supply agencies (e.g., the Global Drug Facility)³¹ to quantify drug requirements and ensure adequate and timely supply of the

required quantity of RPT. Several generic TB drug manufacturers that are part of the global quality-assured TB drug supply chains are located in the WHO South-East Asia Region. They have the capacity to step up drug production to match global demand. Close coordination with them to produce RPT in adequate quantities and at a reduced price is urgently needed. For this to happen, it is essential that the NTPs in the Region officially communicate to all the stakeholders their readiness to scale up RPT-based TPT regimens and the drug volumes of RPT required, so that manufacturers can take note of this and expand capacities and supply chains to meet the demand. In the meantime, countries may also revisit their policies and adopt other WHO-recommended, shorter, non-RPT TPT regimens which are less advantageous, such as 4 months of daily rifampicin or 3 months of daily isoniazid and rifampicin, that are readily available in adequate quantities and use these for TPT scale-up.

Several non-governmental organisations, community-based organisations, and other partners that support the implementation of various TB services in the countries of the Region³² could engage with the NTPs to educate the community about the importance of TPT and enhance the demand for TPT services. Community-based organisations could also help in outreach efforts, and specifically, contact investigations. Several innovative private sector engagement strategies have been tried for TB case finding, and the TPT component should be incorporated into all these efforts to enhance the reach of TPT services in the Region through this sector.³³ Many communication and social mobilisation tools and approaches that are being used to improve the quality of TB care³⁴ can be adapted to improve the demand and acceptability of TPT services.

CONCLUSIONS AND THE WAY FORWARD

The End TB Strategy envisions a world free of TB—zero deaths, disease and suffering by 2030. The COVID-19 pandemic has disrupted the global efforts being made to end TB. The path to achieving these End TB goals needs to have a strong prevention component. TPT is currently one of the major public health interventions to prevent the development of TB disease among high-risk individuals. The WHO SEAR countries are making progress in scaling up TPT services, but as elsewhere in the world, current efforts are grossly insufficient to meet the UNHLM targets and End TB targets. The opportunities outnumber the challenges for TPT scale-up. Advocacy for resource allocation and addressing supply side issues through human resource capacity building, decentralisation of TPT service delivery models, embedding TPT services into ongoing contact investigation and case finding activities, ensuring TPT

drug availability, and addressing demand side issues through community education and engagement are measures that can be considered for the rapid scale-up of TPT services in the Region.

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R É S U M É

En septembre 2018, tous les pays se sont engagés à fournir un traitement préventif de la TB (TPT) à au moins 30 millions de personnes à risque de TB maladie entre 2018 et 2022 lors de la toute première réunion de haut niveau des Nations Unies (UNHLM) consacrée à la TB. Dans la région Sud-est asiatique (SEA) qui représente 44% du poids mondial de la TB, en 2018 et 2019, seulement 1,2 millions de personnes à risque élevé (contacts domiciliaires et personnes vivant avec le VIH) ont reçu le TPT (11% des 10,8 millions ciblés par la région SEA). En 2020, presque tous les 11 pays de la région SEA ont révisé leurs politiques relatives aux groupes cibles et aux critères d'éligibilité du TPT et ont

adopté au moins un protocole court recommandé dans les dernières directives de l'OMS. Les défis principaux à l'accélération du TPT dans le région SEA sont le manque de ressources, les connaissances et la prestation des services, les lacunes de la couverture parmi les prestataires de soins et les bénéficiaires des services et assurer la disponibilité de quantités suffisantes de rifampine pour les protocoles plus courts de TPT. Il y a plusieurs opportunités régionales pour faire face à ces lacunes et les pays de la région SEA doivent profiter de ces opportunités pour accélérer les services de TPT rapidement afin de réduire le poids de la TB dans la région SEA.
