

Summary report on the

**Intercountry workshop on
transition towards new
policies and treatments for
drug-resistant tuberculosis
and latent tuberculosis
infection management**

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Lahore, Pakistan
29 April–1 May 2019



REGIONAL OFFICE FOR THE

**World Health
Organization**

Eastern Mediterranean

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Contents

1.	Introduction.....	1
2.	Summary of discussions	3
3.	Conclusions.....	8
4.	Recommendations.....	10

1. Introduction

Worldwide, tuberculosis (TB) is one of the top 10 causes of death and one of the leading causes from a single infectious agent (above HIV/AIDS). Globally, in 2017, an estimated 10 million people fell sick with TB. About 23% of the world's population (1.7 billion people) are estimated to have latent TB infection (LTBI) and are at increased risk of developing active TB disease during their lifetime. Moreover, drug-resistant TB remains a threat. The World Health Organization (WHO) estimates that around 230 000 people died and there were 558 000 new cases of multidrug-resistant TB (MDR-TB)/rifampicin-resistant TB (RR-TB) in 2017.

The TB burden in the WHO Eastern Mediterranean Region is estimated at 771 000 incident cases annually, with 523 494 (68%) cases reported during 2017. Only 4253 (20%) MDR-TB cases in the Region started treatment out of an estimated 21 000, and only 62% were successfully treated. In addition, there are gaps in latent TB diagnosis and TB preventive therapy in the Region and globally.

WHO published updated and consolidated guidelines for programmatic management of LTBI in 2018 and announced landmark changes in drug-resistant TB treatment in 2019. These changes will bring major improvements in treatment outcomes and quality of life for TB patients. In order to ensure TB preventive treatment and more effective treatment for drug-resistant TB, national TB programmes, partners and supporting agencies need to rapidly introduce these new WHO recommendations.

With this in mind, the WHO Regional Office for the Eastern Mediterranean organized an intercountry workshop to bring together national TB programmes from the Region and key partners to discuss a rapid transition towards the new policies recommended for the

programmatic management of drug-resistant TB and LTBI, the implications for country implementation, and partner perspectives and support.

The workshop was held from 29 April to 1 May 2019 in Lahore, Pakistan, and was attended by 70 participants from 16 countries, including Afghanistan, Iran (Islamic Republic of), Iraq, Jordan, Lebanon, Libya, Morocco, Pakistan, Qatar, Saudi Arabia, Somalia, Sudan, Syrian Arab Republic, Tunisia, United Arab Emirates and Yemen, as well as WHO staff from headquarters, regional and country levels, and partners, including the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), International Organization for Migration (IOM), Stop TB Partnership, United States Agency for International Development (USAID), United Nations Development Programme (UNDP) and some nongovernmental organizations from Pakistan.

The objectives of the workshop were to:

- share the key changes in MDR-TB WHO policy and treatment guidelines and LTBI management and discuss the implications for country implementation;
- discuss partner perspectives in supporting the transition towards scaling-up new MDR-TB treatment and LTBI management;
- share country experiences in programmatic management of drug-resistant TB and LTBI;
- assist countries in the process of operationalization of the new guidelines and the development of country plans for transition and implementation; and
- harness the new commitments and strategies to end the TB epidemic, following the United Nations (UN) General Assembly high-level meeting on the fight to end TB held in September 2018.

Dr Palitha Mahipala, WHO Representative in Pakistan, delivered an opening message from Dr Ahmed Al-Mandhari, WHO Regional Director for the Eastern Mediterranean. In his message, Dr Al-Mandhari outlined the TB and MDR-TB epidemics in the Eastern Mediterranean Region, the progress achieved and the challenges facing the TB response. He urged a transition towards the new WHO policies on MDR-TB and LTBI management so that patients can benefit from improved treatment outcomes and quality of life.

Dr Assad Hafeez, Director-General of Health, Federal Ministry of National Health Services, Regulations and Coordination of Pakistan, in his address, emphasized that ending TB was a priority for Pakistan, fully supported by the Government and the Minister of Health, within the context of achieving universal health coverage and the Sustainable Development Goals (SDGs). Dr Hafeez expressed Pakistan's commitment to ending the TB epidemic by 2030 through sustainable funding and adaptation of the WHO multisectoral accountability framework.

2. Summary of discussions

UN General Assembly Political Declaration on TB and multisectoral accountability framework

Presentations were made on the TB situation in the Region, the UN General Assembly high-level meeting on TB and the resulting Political Declaration on TB, and WHO's multisectoral accountability framework and its implementation.

Changes in WHO drug-resistant TB treatment guidelines and their implications for country implementation

Participants were briefed on key changes to WHO's guidelines on drug-resistant TB treatment and the implications for country implementation. Significant changes were outlined in: MDR-TB drug classification; treatment composition, regimen and duration; monitoring patient response to MDR-TB treatment; and patient care and support.

The implications for country implementation may include the following changes: active TB drug-safety monitoring and management (aDSM); drug-sensitive testing (molecular and phenotypic) at start of treatment; monthly culture monitoring; ambulatory care and TB care and support with the appropriate treatment administration involving the community, health care workers or using video communication technology for video-observed treatment; and the engagement of the community in identifying the side-effects of second-line TB drugs and for TB patient referral to primary health care facilities.

A presentation was given on the support available for country implementation of the new MDR-TB guidelines through the regional Green Light Committee (rGLC) network mechanism. Presentations were also made on aDSM for MDR-TB medicines, operational research for new regimens and innovations, and laboratory requirements in support of a smooth transition to the new MDR-TB treatments. Experiences were shared by countries that had already started the transition process for introduction of the new MDR-TB treatment regimens and had made progress on implementation of active drug-safety management.

LTBI treatment and changes in the WHO LTBI guidelines

A presentation was given on the current global status of LTBI treatment and changes to the WHO updated and consolidated guidelines for programmatic management of LTBI, focusing on the key recommendations for LTBI diagnosis and treatment, identification of risk groups, algorithms to rule out TB, testing options for LTBI, and preventive TB treatment options. It outlined how to reach the targets of the UN General Assembly's Political Declaration on TB regarding preventive treatment for 30 million persons, through improving LTBI diagnosis and treatment for people living with HIV and household contacts < 5 years.

However, expanding LTBI testing and treatment to all household contacts > 5 years and clinical risk groups remains a challenge for many countries, representing about two thirds of the 30 million people being targeted globally for preventive therapy by 2022.

Countries are recommended to adapt and develop the algorithms to rule out TB in specific populations such as people living with HIV on antiretroviral therapy, older household contacts, contacts of MDR-TB patients and other risk groups, and to consider the use of tests for infection (tuberculin skin tests/interferon-gamma release assay) and chest radiography in high-burden country settings and the introduction of preventive treatment regimens. Monitoring and evaluation tools and indicators also need to be developed.

The implications for the private sector, community providers and occupational health settings must be taken into account when rolling out these new policies and guidelines.

Partner support for the transition towards the new MDR-TB and LTBI policies and treatments

Presentations were made on the approaches of the Global Fund, IOM and Stop TB Partnership and their support for the transition towards the new MDR-TB and LTBI policies and treatments. Key contributions of the Global Fund include: scaling-up drug-resistant TB management globally through implementation of new diagnostic tests; providing treatment to more than 370 000 patients with drug-resistant TB during 2002–2016 and an additional 102 000 drug-resistant TB patients in 2017; and supporting the transition to the new MDR/RR-TB regimens through the rGLC mechanism.

To support the transition towards the new WHO MDR-TB policies, the Global Fund has been involved in discussions with WHO and other partners, before and after WHO's rapid communication on the subject, and no longer supports the procurement of drugs not recommended by the new guidelines for drug-resistant TB treatment. The Global Fund is reviewing the implications of the new recommendations and is in ongoing consultation with national TB programmes and partners to identify countries ready for transition and sources of the required additional funding.

The Global Drug Facility and Stop TB Partnership can help countries with the procurement of drugs for TB preventive treatment, as well as for treatment of MDR-TB for countries with Global Fund funding as well as domestic funding. Countries need to consider their existing stocks of second-line TB drugs and the availability of the new recommended oral regimen drugs before deciding on transitioning to the all-oral drugs for MDR-TB.

Many countries expressed a need for technical support, capacity-building and guidance for implementation of programmatic management of drug-resistant TB and the transition to implementing the new and consolidated guidelines on drug-resistant TB treatment and programmatic management of LTBI.

Developing transition plans for the new guidelines on drug-resistant TB treatment and programmatic management of LTBI

In working groups, participants identified the key actions needed to move forward on the introduction and roll out of the new WHO policies for treatment of drug-resistant TB and programmatic management of LTBI.

Draft timelines for programmatic management of LTBI were developed by 14 countries, with key milestones identified for 2019–2020. In all countries, national TB strategic plans are either already updated and include the 2018 WHO LTBI guidelines or will be updated before the end of 2019. National TB guidelines in all countries are also in line with the 2018 WHO LTBI guidelines or will be updated by the end of 2019, except Iraq. Most countries have reporting and/or electronic data management in place for reporting LTBI management among people living with HIV and child and other household contacts, with four countries planning this for 2020.

Achieving treatment coverage among all key risk groups is challenging. There is a tendency for countries with the larger TB caseloads in the Region to defer action to increase coverage in all three priority risk groups until 2020. Moreover, several countries do not expect to achieve 100% coverage in certain groups by the end of 2020; for instance, only 25% and 50% coverage of household contacts > 4 years in Pakistan and Afghanistan, respectively, is expected by the end of 2020. Furthermore, only three countries report that rifapentine is on their essential

medicines list. Most other countries will add it by the end of 2019, but in four countries this will only be possible by the end of 2020.

Countries also discussed the timelines and preparation needed for the transition to the new guidelines on drug-resistant TB treatment, including the updating of national drug-resistant TB guidelines, training staff, laboratory requirements and diagnostic expansion plans, quantification and procurement of second-line anti-TB drugs, aDSM establishment, and patient care and support.

Two countries have already started implementation of the new recommendations (Morocco and Tunisia). The rest are in the advanced stages of preparation, with certain components already in place and plans to transition by the end of 2019 (Afghanistan, Islamic Republic of Iran, Lebanon, Libya, Pakistan, Qatar, Saudi Arabia, Somalia, Sudan, United Arab Emirates and Yemen). Iraq is facing resistance from some in-country stakeholders to using the new drugs and regimens, and expects a significant delay in the transition until the end of 2020, with a pilot project planned for the first quarter of 2020. Syrian Arab Republic is planning to start implementation in the second quarter of 2020 due to the security challenges in the country. Two countries (Pakistan and Somalia) expressed an interest in also using the modified shorter regimen, under operational research conditions.

3. Conclusions

- LTBI treatment coverage will be challenging, especially among household contacts > 5 years, which represent about two thirds of the 30 million people being targeted globally for preventive therapy by 2022. Action on the programmatic management of LTBI in several countries will need close review and follow-up to

improve understanding of the implications for achieving the related targets.

- Most countries in the Region are at various stages of the transition towards implementation of the new WHO consolidated guidelines on drug-resistant TB treatment.
- Countries identified the need for technical support for implementation of programmatic management of drug-resistant TB and the transition to implementing the new and consolidated guidelines on drug-resistant TB treatment and programmatic management of LTBI. This included support for (by country): updating the national strategic plan to reflect the transition towards the new guidelines on drug-resistant TB treatment and programmatic management of LTBI (Iraq, Pakistan, Syrian Arab Republic, Yemen); laboratory expansion for line probe assay (Libya, Yemen) and culture and second-line phenotypic drug-susceptibility testing (Libya, Sudan for new drugs); guideline update (Morocco, Somalia, Syrian Arab Republic, Yemen); training (Libya, Somalia, Sudan, Syrian Arab Republic, Yemen); aDSM (Iraq, Lebanon, Pakistan, Yemen); procurement and supply management quantification (Sudan); infection control (Islamic Republic of Iran, Iraq); and a WHO/rGLC mission to advocate for early drug-resistant TB transition with the Ministry of Health and stakeholders (Iraq).
- There is a need for a concerted global effort, involving ministries of health, technical partners, researchers and donors, to identify the best way forward for achieving the targets of the UN General Assembly's Political Declaration on TB.

4. Recommendations

To Member States on transition to the new guidelines on drug-resistant TB treatment

1. Immediately start preparation for the transition, including for the preparation/finalization of action plans, updating of guidelines, setting up aDSM, procurement and supply management, laboratory expansion and drug-susceptibility testing/line probe assay, and patient support.
2. Start implementation of the new drug-resistant TB treatment recommendations as early as possible in order to offer optimal treatment to MDR/RR-TB patients.
3. Establish funding estimates for the transition and mobilize support and resources from potential funding sources, including domestic sources, the Global Fund and others.
4. Identify needs for technical support to support the transition process from technical partners such as WHO and others, and principal recipients of Global Fund TB grants (in relevant countries).

To Member States on the transition to the new guidelines for programmatic management of LTBI

5. Be realistic in programmatic management of LTBI transition planning. The task is substantial; a change of culture and practice in LTBI management is needed to accelerate progress to achieve the UN targets for 2022.
6. Match the revision of the national strategic plan, including the LTBI component, with the mobilization of sufficient resources.
7. Update national guidelines with appropriate diagnostic algorithms and treatment.

8. Achieve national coverage for LTBI treatment of all key risk groups through nationwide activities including the training of community care services, engaging HIV and primary care services, and procuring diagnostics test and new regimens.
9. Address local barriers to LTBI in any planned operational research.

To WHO and partners

10. Continue to provide guidance and technical support to countries in close collaboration and consultation with partners and stakeholders for a smooth transition towards the new guidelines for WHO drug-resistant TB treatment and programmatic management of LTBI through the rGLC network and other potential mechanisms.
11. Ensure close follow up with countries for transition planning finalization and implementation.
12. Establish regular assessment of progress and achievements in reaching MDR-TB and LTBI targets.



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