IMPLEMENTING THE END TB STRATEGY: THE ESSENTIALS
2022 UPDATE
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Acknowledgements

The 2022 updated version of Implementing The End TB Strategy: The Essentials was produced by a core team of 5 people: Hannah Monica Dias, Prudence Smith, Yi Wang and Anna Stukalova, under the overall guidance of the Director of the Global TB Programme, Tereza Kasaeva. Additional inputs to sections were provided by Farai Mavhunga, Matteo Zignol, Dennis Falzon, Kerri Viney, Ernesto Jaramillo, Marzia Calvi, Delia Boccia and Liana Oganezova.

Abbreviations

- AIDS acquired immunodeficiency syndrome
- ART antiretroviral therapy
- BCG bacille Calmette-Guérin
- CSTFe WHO Civil Society Task Force
- CI confidence interval
- COVID-19 coronavirus disease 2019
- DR-TB drug-resistant TB
- DST drug susceptibility testing
- Global Fund The Global Fund to Fight AIDS, Tuberculosis and Malaria
- Global Plan2 Global Plan to End TB, 2018–2022
- GTB WHO Global Tuberculosis Programme
- HIV human immunodeficiency virus
- IGRA interferon-gamma release assay
- IPC infection prevention and control
- MAF-TB multisectoral accountability framework for tuberculosis
- MDR-TB multidrug-resistant TB
- NCD non-communicable diseases
- NGO nongovernmental organization
- NSP national TB strategic plan
- NTP national TB programme
- PHC primary health care
- PLHIV people living with HIV
- PMTCT prevention of mother-to-child transmission (of HIV)
- PPM public-private mix
- RR-TB rifampicin-resistant tuberculosis
- SDG Sustainable Development Goals
- TB tuberculosis
- TST tuberculin skin test
- UHC universal health coverage
- WHA World Health Assembly
- WHO World Health Organization
TB remains one of the world’s deadliest infectious killers. It poses a severe global threat that disproportionately affects the poorest and most vulnerable and is an enormous human and societal toll for what is essentially, a curable and preventable disease.

Since the adoption of the End TB Strategy of the World Health Organization (WHO) and the United Nations Sustainable Development Goals in 2015, the world has witnessed growing political commitment and action to end the TB epidemic.

The first WHO Global Ministerial Conference on TB convened in 2017 resulted in the Moscow Declaration to End TB which articulated the key conditions for success - universal access to health care, multisectoral action and accountability, financing and research. This Declaration was subsequently endorsed at the World Health Assembly in 2018.

In 2020, the COVID-19 pandemic destabilized the global economy and reversed progress in health and development globally. TB care and prevention was particularly affected, with the redirection of human, financial and other resources to the COVID-19 response. Furthermore, public health measures resulted in reducing access to TB diagnosis and treatment services.

A special report released by the United Nations Secretary-General António Guterres in 2020, developed with the support of the WHO Director General, outlined 10 priority recommendations to galvanize urgent and more ambitious investments and actions, especially in the context of the COVID-19 pandemic.

This document - "Implementing the End TB Strategy: The Essentials" describes the important elements of operationalizing the principles, pillars and components of the End TB Strategy after providing an understanding of the vision, goal, targets, and milestones of the Strategy. The latest guidelines and tools are showcased linked to each pillar of the Strategy. The document builds upon WHO’s strategy, the Thirteenth General Programme of Work, 2019–2025 (GPW 13) that focuses on delivering measurable improvements to health in all countries and on the priorities set in the WHO Global Action Plan for Healthy Lives and Well-being for All (SDG3 GAP) that brings together 13 multilateral health, development and humanitarian agencies to better support countries to accelerate progress towards the health-related Sustainable Development Goals (SDGs) including for TB.

The pandemic has highlighted the critical need to maintain quality essential health services during emergencies. National strategic planning is a critical step for ensuring that the country level TB response can cope with changing contexts. We hope the resources contained in Implementing the End TB Strategy: The Essentials will help to strengthen the implementation of the End TB Strategy in all countries and contribute towards ending the suffering from this ancient disease.

Dr Tereza Kasaeva
Director, Global Tuberculosis Programme, World Health Organization
“Implementing the End TB Strategy: The Essentials 2022” is a comprehensive compendium of essential published guidelines, policies and resources which describe the actions needed at national level to achieve the ambitious global goal of ending the TB epidemic by fully implementing the World Health Organization’s End TB Strategy.

Developed by the WHO’s Global Tuberculosis Programme, the compendium summarizes and updates the 2015 version, Implementing the End TB Strategy: The Essentials and collects all new and available guidance in one publication. Intended as a resource for national TB programmes (NTP’s) and all stakeholders engaged in TB care and prevention, it emphasizes the need to prepare detailed national operational guidance on the implementation of the End TB Strategy to meet the needs of individual countries and diverse stakeholders. This is a “living document” and will be updated as more resources and guidelines are developed or revised.

This compendium is organized into five parts:

- **Part ONE** describes the approach and the principles underpinning the End TB Strategy.
- **Part TWO** explains the global targets and summarises progress to date.
- **Part THREE** presents all the available guidance under the three key pillars of the End TB Strategy:
  - Pillar 1: Integrated, patient-care and prevention
  - Pillar 2: Bold policies and supportive systems
  - Pillar 3: Intensified research and innovation
- **Part FOUR** describes guidance and approaches to TB prevention and care in the context of COVID-19.
- **Part FIVE** details the way forward and 2020 recommendations from the UN General Assembly.
INTRODUCTION, APPROACH AND PRINCIPLES OF IMPLEMENTING THE END TB STRATEGY

PART ONE
Introduction

- The World Health Organization’s (WHO) annual global TB reports (1) chronicle progress made through widespread implementation of the global targets outlined in the End TB Strategy (2) and political declaration of the 2018 UN high-level meeting (UNHLM) on TB (3).

- The COVID-19 pandemic coupled with ongoing crises such as armed conflict, increasing food insecurity, political and economic instability, has reversed years of progress made in the fight against TB. For the first time in nearly two decades, WHO reported an increase in the number of people falling ill with TB and drug-resistant TB in 2021, alongside an increase in deaths. Getting back on track will require a revitalization of efforts by all countries.

- National TB programmes will require greatly enhanced support from all stakeholders for proper implementation of the End TB Strategy especially in the context of the COVID-19 pandemic, with robust multisectoral engagement and accountability.
Progress in ending the TB epidemic will depend on:

- Optimizing current strategies and interventions for TB care and prevention;
- Achieving universal access to TB care and support within Universal Health Coverage (UHC) and social protection and addressing social determinants of TB – as part of the global development objectives to eliminate poverty and address inequity;
- Investing in research to develop new, better and rights-based tools and strategies for diagnosis, treatment and prevention of TB.

The End TB Strategy encompasses a package of interventions that can be fully adapted at country level. It has ten components organized under three pillars and executed according to four underlying principles. Intensified action, from and beyond the ministries of health, in close collaboration with all stakeholders including other ministries, communities, civil society and the private sector, is essential.
Government stewardship and accountability, with monitoring and evaluation

Strong coalition with civil society organizations and communities

Protection and promotion of human rights, ethics and equity

Adaptation of the strategy and targets at country level, with global collaboration
The imperative of multisectoral collaboration and accountability

Multisectoral collaboration and accountability is key to successful implementation of the End TB Strategy. The mix of biomedical, public health and socioeconomic interventions required, combined with research and innovation, results in a portfolio far beyond the remit of NTPs. With high-level support, the NTP leadership will need to cultivate and steer the engagement of a wide range of collaborators including ministries such as social welfare, labour, justice, education, transport and science and technology; technical and scientific institutions; financial partners and development agencies; civil society; and the private sector.

NTPs or their equivalent may be better placed to coordinate the delivery of TB care and prevention through general health services, while ministers of health and directors-general of health services or equivalents can provide the leadership needed to reinforce and enforce a regulatory framework, and facilitate inter-ministerial and intersectoral collaboration.

WHO has developed and released the Multisectoral Accountability Framework on TB (MAF-TB) in 2019 (7), and is supporting countries in its adaptation and implementation. The main aim of the MAF-TB is to support effective accountability of governments and all stakeholders, at global, regional, and country levels, in order to accelerate progress to end the TB epidemic. Since 2019, WHO has been working with some of the biggest high-burden countries to ensure the inclusion of accountability mechanisms and measures in national budget planning and pursuing assessment during joint reviews of national programmes with independent and civil society representatives. WHO also supported the creation and/or reinforcement of high-level collaboration and review mechanisms, broad stakeholder forums, as well as head-of state or government initiatives, in pathfinding countries including India, Indonesia, and Viet Nam.

Importance of multisectoral engagement to end TB: Contribution of different SDGs
Principles underlying the End TB Strategy

1. Government stewardship and accountability with monitoring and evaluation

Government stewardship is fundamental to implementing and achieving the targets and goal of the End TB Strategy. A comprehensive response will require involvement of authorities from health and social sectors as well as from other ministries. Stewardship responsibilities may be shared by all levels of government – central, provincial, and local. Within the ministries of health, disease control divisions and NTPs may continue providing technical and strategic support for TB care and prevention services, while eliciting active engagement of higher authorities within the health ministry and their counterparts in other ministries. Governments need to create and support mechanisms to actively involve TB-affected communities, patients, TB survivors, and health workers in responding to the TB epidemic.

Monitoring and evaluation have to be regular and systematic to ensure accountability. Joint review processes need to include data collection and validation in addition to independent assessments. They should use quantitative and qualitative information and engage those targeted and served. The use of digital tools should be progressively introduced, and systems to improve performance and impact should be well-defined and supported. At the same time, deficiencies in fulfilling roles and responsibilities should be promptly addressed.

2. Strong coalition with civil society organizations and communities

Representatives of TB-affected communities and civil society organizations should participate actively in all stages of End TB Strategy implementation, including programme planning and design, service delivery, and monitoring and evaluation. The engagement and leadership of strong coalitions of civil society organizations and communities will help empower “people with TB” and remove the “living with” TB or living with any TB-related impairment or disability and vulnerable populations with a voice and an active role, accelerating the response to the TB epidemic and improving the use of quality services.

This engagement is also essential for disseminating information, providing education and support to people with TB and their families, promoting investment in TB research and strengthening grassroots advocacy. It is critical that government authorities make concerted efforts to engage and support civil society in TB care and prevention.

WHO Civil Society Taskforce on TB

WHO’s Civil Society Task Force on TB (CSTF) was established in December 2018 as a platform for dialogue and exchange to harness the untapped potential in civil society engagement and accelerate progress to End TB. The taskforce helps mainstream civil society and affected community perspectives in the TB response at all levels. Task Force members are helping to guide and coordinate stakeholder perspectives for rapid adoption of, and access to, newly-recommended treatments and the formalization of mechanisms for civil society engagement, with a focus on social protection, parliamentarian engagement, amplification of the voices of TB survivors, advocacy for increased domestic funding, sharpening focus on and attention to the marginalized and most vulnerable, TB research, addressing social, legal and gender barriers to care, and strengthened accountability.
A human rights-based approach that includes respect for ethical values and promotion and pursuit of equity, is a key principle of the End TB Strategy. Health is a human right, along with access to high-quality care and social protection. Replace with: Progress on these rights will help reduce risk factors for TB infection, disease, enable far better outcomes for those affected and contribute to the mitigation of the impact of TB-related impairments and disabilities. For all interventions described in this document, applying a human rights-based approach means a pursuit of non-discrimination and to replace with equity, participation and inclusion, and accountability. In practical terms, this means that policies, services and practices should protect and promote individual human rights as well as address the underlying inequities of the poor and marginalized communities who bear a greater burden of TB infection, disease, deaths and social impacts.

Efforts should be made to identify and eliminate human rights violations that could affect access to quality care or prevention, directly or indirectly. For example, migrants, detainees, prisoners or persons who use drugs may face restrictions on their freedom which can prevent access to care and full treatment, without due process or potential for redress.

NTPs, their partners and relevant stakeholders should identify, acknowledge and address practices that are not based on sound ethical standards, and that fail to protect and promote human rights. These should be guided by globally recognized principles and values, sensitive to local values and traditions, and be informed by debates among all stakeholders.

3. Protection and promotion of human rights, ethics and equity

Ethics guidance for the implementation of the End TB Strategy

WHO Ethics Guidance aims to help ensure that countries implementing the End TB Strategy adhere to sound ethical standards to protect the rights of all those affected. The guidance addresses contentious issues such as, the isolation of contagious patients, the rights of TB patients in prison, discriminatory policies against migrants affected by TB, among others. It emphasizes five key ethical obligations for governments, health workers, care providers, nongovernmental organizations, researchers and other stakeholders to:

- provide patients with the social support they need to fulfil their responsibilities
- refrain from isolating TB patients before exhausting all options to enable treatment adherence and only under very specific conditions
- enable “key populations” to access same standard of care offered to other citizens
- ensure all health workers operate in a safe environment
- rapidly share evidence from research to inform national and global TB policy updates.
The End TB Strategy is not “one size fits all” and must be tailored to diverse country settings. It requires a new or updated medium-term, prioritized and costed national TB strategic plan (NSP). For this reason, baseline assessments will be needed including: mapping of persons at a greater risk, understanding socioeconomic contexts, analyzing access barriers, especially for vulnerable populations, and a grasp of the health system context including underserved areas and inequitable service delivery. The baseline assessments will help prioritize interventions and approaches and clarify diverse needs and capacities on the ground. National adaptation will require the development of clear guidance on how to implement the different components, based on local evidence and opportunities. Countries need to set their own national targets guided by the ambitious global goal, but taking into account national circumstances.

Tackling the global TB epidemic effectively requires close collaboration among countries, essential for national health security. Countries within a region can benefit from regional collaboration. Migration within and between countries poses challenges and addressing them will require both in-country coordination and cross-border collaboration. Global coordination is also essential to mobilize resources for TB care and prevention from diverse multilateral, bilateral and domestic sources.
ABCD’s of ongoing support required to implement the End TB strategy in countries

Advocacy

High-level political commitment and national mechanisms to direct the adaptation and implementation of the Strategy

Multisectoral collaboration and national mechanisms to direct the adaptation and implementation of the Strategy

Strategic advocacy and communications

A high-level spotlight on ending TB critical to drive increased action and investments. To facilitate this, there is need for a strong targeted advocacy and resource mobilization plan. Strategic advocacy and communications across all three levels global, regional and national is vital.

Effective implementation of the End TB Strategy requires multisectoral engagement and accountability with the involvement of all stakeholders, including different government departments across ministries. Having in place a high-level national coordination and review body/mechanism to oversee the multisectoral TB response is important for the overall coordination, harmonization and alignment of activities undertaken by different government sectors and other stakeholders.

Advocacy should not only cover key TB milestones and events such as World TB Day, but also go beyond TB-specific activities to leverage advocacy and promotion efforts around linked areas such as Universal Health Coverage, antimicrobial resistance, non-communicable diseases and pandemic preparedness efforts. Innovative approaches and the latest tools for communications including on social media should be utilized actively for wide outreach.

National governments, partners, civil society and other stakeholders need to continually raise the profile of national TB efforts to send a clear message that the government and its partners are accelerating efforts to end TB. Collaboration should include partners beyond the TB community.

Bolster and re-energize the response

TB situation: “Know your epidemic”

Current status of response and health system capacity

Policy and regulatory environment

Ministries of health may need to enhance their support to NTPs by realigning their NSPs to respond to changing circumstances and crises, such as the ongoing pandemic, through inclusive stakeholder consultations and collaboration. A comprehensive health system assessment and epidemiological mapping would help identify and prioritize populations at risk and communities with poor access to services.

In addition to TB-specific interventions, continuous assessments would highlight the status of coverage of TB diagnostics, treatments for drug-resistant TB, and related general health and social welfare initiatives. This would also provide a better understanding of how to prioritize the place of TB in, for example, health-related regulatory frameworks, the national plan for UHC and various various social protection schemes.
Coordination and collaboration across all sectors

Across relevant ministries and departments, such as health, finance, education, food, social-welfare, justice, labour, transport, and migration with
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People with TB, people with TB-associated disability, affected communities and civil society

the private sector

national and international supporters and partners

A high-level multi-stakeholder coordinating mechanism led by the national government can significantly enhance the implementation of the End TB Strategy by enabling
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Proper oversight of the implementation of the new strategy;

Advocacy for required resources;

Development of a participatory platform for all health and non-health stakeholders;

Facilitating intersectoral collaboration and;

Advising the NTP through frequent stakeholder consultations, ongoing internal monitoring and periodic independent external evaluations.

Establishing and maintaining a high-level coordinating mechanism should be informed by lessons learned from similar efforts in other health and social sector programmes.

Digitalize

Harnessing the power of digital technologies and health innovation to enable people centered care

For the End TB Strategy’s objectives to be realised, there is a need for novel solutions to address the challenges posed by TB to health professionals, and to affected people and communities. Information and communication technology presents opportunities for innovative approaches to support TB efforts in patient care, surveillance, programme management and electronic learning. The effective application of digital health products at a large scale and their continued development need the engagement of TB patients, survivors and their caregivers, innovators, funders, policy-makers, advocacy groups, and affected communities.

WHO has released a digital knowledge sharing platform and End TB E-Learning Courses on OpenWHO to support roll out and implementation of the latest guidelines and tools.
VISION, GOAL, TARGETS, MILESTONES AND PROGRESS TO DATE

Part 2 presents the vision and the ambitious goal of the End TB Strategy as well as the milestones and targets to achieving the goal of ending the global TB epidemic.

Part 2 also highlights progress to date in reaching the global targets.
Vision and goal

The vision of the End TB Strategy is “a world free of TB”, also expressed as “zero deaths, disease and suffering due to TB”. All countries could use this vision in national strategies and plans, without need for adaptation.

Global indicators, targets and milestones

Global targets for TB have been set in the SDGs(4), the End TB Strategy and the political declaration of the UN high-level meeting on TB (Table 1). The SDG and End TB Strategy targets are for reductions in the burden of disease caused by TB, measured as TB incidence (new cases per 100 000 population per year), the number of TB deaths and the percentage of TB patients and their households that face catastrophic costs. The political declaration reaffirmed these targets while also setting new targets for access to TB treatment, access to TB preventive treatment and increased financing.

In addition to targets for 2030, the End TB Strategy defines 2020 and 2025 milestones for reductions in TB incidence and the number of TB deaths. The 2020 milestones are a 20% reduction in TB incidence and a 35% reduction in the number of TB deaths, compared with levels in 2015.

The three high-level indicators of the End TB Strategy – reductions in TB deaths, reductions in the TB incidence rate and elimination of catastrophic costs – are relevant to all countries. However, targets and milestones for these indicators can be adapted by countries to reflect such factors as different starting points, the main drivers of local epidemics, national policy and strategy related to universal health coverage (UHC) and social protection and planned interventions. Countries need to set their own national targets guided by the global level of ambition but taking into account national circumstances.

Key elements contributing towards reaching targets include optimum use of existing interventions, achievement of UHC for essential prevention, treatment and care interventions as well as efforts to address the social determinants and consequences of TB, and consequences of TB, including TB-associated impairments and disabilities.

In addition, there needs to be an intensification of research and innovation to bolster the availability and wide use of new tools, including pre- and post-exposure vaccines; point-of-care diagnostic tests for infection and disease and shorter treatment regimens for TB disease and infection. There is also a need for new tools for the diagnosis and treatment of TB-associated impairment and disability and to test efficient models for the optimal integration of social protection and TB care services.

Reliable measurement of progress in reducing TB incidence, and TB deaths is essential, as well as special surveys to measure catastrophic costs and social protection coverage among TB-patients and their families.
The UN high-level meeting political declaration reaffirmed the global TB targets set in the SDGs and the End TB Strategy and set new targets for TB treatment, TB preventive treatment and funding (Table 1).

### UN High Level meeting on TB sets new targets

Table 1. Global TB targets set in the Sustainable Development Goals (SDGs), the End TB Strategy and the political declaration of the UN high-level meeting on TB

<table>
<thead>
<tr>
<th>SDG Target 3.3</th>
<th>By 2030, end the epidemics of AIDS, TB, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases</th>
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</table>
| End TB Strategy                                                                 | 80% reduction in TB incidence by 2030, compared with 2015  
2020 milestone: 20% reduction  
90% reduction in the number of TB deaths by 2030, compared with 2015  
2020 milestone: 35% reduction  
No TB-affected households face catastrophic costs by 2020 |
| UN high-level meeting on TB                                                                 | 40 million people treated for TB from 2018–2022, including:  
- 3.5 million children  
- 1.5 million people with drug-resistant TB, including 115 thousand children  
At least 30 million people provided with TB preventive treatment from 2018–2022, including:  
- 6 million people living with HIV  
- 4 million children under 5 years of age and 20 million people in other age groups who are household contacts of people affected by TB  
Funding of at least US$ 13 billion per year for universal access to TB prevention, diagnosis, treatment and care by 2022  
Funding of at least US$ 2 billion per year for TB research from 2018–2022 |
Indicators for monitoring global and national progress in implementing the main components of the End TB Strategy, and recommended target levels

In addition to the three high-level End TB Strategy targets discussed in the previous section, operational indicators and associated targets are required to monitor implementation of the ten components of the End TB Strategy. These indicators and targets should allow reliable monitoring of progress within a national planning cycle, typically 3-5 years. Ideally, these indicators should be measured annually to help foster accountability for achievement of targets, prompt changes to policy, strategy and interventions when targets are not on track to be met, and allow regular and accurate assessments of progress. Measurement at a disaggregated level, for example for specific subpopulations or geographical areas, is also desirable to allow for better adaptation of the country response.

A top-ten list of operational indicators relevant to both global and national monitoring of progress in implementing the End TB Strategy is provided in Table 2. This table also defines the recommended target level for each indicator and explains the rationale for its inclusion in the “top-ten”.

A common target year for all countries is not recommended; instead, when adapting the End TB Strategy at national level, the year in which the target level is expected to be achieved should be clearly defined for each indicator. Some countries will have already achieved the recommended target level, with targets set to sustain or improve upon the current level. In other countries, the target year will need to be defined in relation to the baseline situation and the anticipated speed and scale at which the necessary improvements can be made. It is suggested that all countries aim to reach the target level at the latest by 2025 to enable achievement of the 2025 global milestones of the End TB Strategy.

Top-ten priority indicators (not ranked) for Monitoring implementation of the end tb strategy at Global and national levels, with recommended target Levels that apply to all countries

The target level is for 2025 at the latest.

<table>
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<th>INDICATOR</th>
<th>RECOMMENDED TARGET LEVEL</th>
<th>MAIN RATIONALE FOR INCLUSION IN TOP-TEN</th>
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<tr>
<td><strong>1. TB TREATMENT COVERAGE</strong></td>
<td>≥ 90%</td>
<td>High coverage of appropriate treatment is a fundamental requirement for achieving the milestones and targets of the End TB Strategy. In combination, it is likely that these two indicators will be used as tracer indicators for monitoring progress towards UHC within the SDGs.</td>
</tr>
<tr>
<td>Number of new and relapse cases that were notified and treated, divided by the estimated number of incident TB cases in the same year, expressed as a percentage.</td>
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<tr>
<td><strong>2. TB TREATMENT SUCCESS RATE</strong></td>
<td>≥ 90%</td>
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</tr>
<tr>
<td>Percentage of notified TB patients who were successfully treated. The target is for drug-susceptible and drug-resistant TB combined, although outcomes should also be reported separately.</td>
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### INDICATOR

**3. PERCENTAGE OF TB-AFFECTED HOUSEHOLDS THAT EXPERIENCE CATASTROPHIC COSTS DUE TO TB**

Number of people treated for TB (and their households) who incur catastrophic costs (direct and indirect combined), divided by the total number of people treated for TB.

**Recommended Target Level:** 0%

**Main Rationale for Inclusion in Top-Ten:** One of the End TB Strategy’s three highlevel indicators; a key marker of financial risk protection (one of the two key elements of UHC) and social protection for TB-affected households.

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**4. PERCENTAGE OF NEW AND RELAPSE TB PATIENTS TESTED USING A WHO-RECOMMENDED RAPID TEST AT THE TIME OF DIAGNOSIS**

Patients tested using a WHO-recommended rapid test at the time of diagnosis, divided by the total number of new and relapse TB patients, expressed as a percentage.

**Recommended Target Level:** ≥ 90%

**Main Rationale for Inclusion in Top-Ten:** Accurate diagnosis is a fundamental component of TB care. Rapid molecular diagnostic tests help to ensure early detection and prompt treatment.

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**5. TB PREVENTIVE TREATMENT COVERAGE**

Percentage of eligible people provided with TB preventive treatment (household contacts of people diagnosed with TB and people with HIV).

**Recommended Target Level:** ≥ 90%

**Main Rationale for Inclusion in Top-Ten:** Preventing TB infection and stopping progression from infection to disease are critical to reduce TB incidence to the levels envisaged by the End TB Strategy. Reduction in TB incidence is also an indicator that has been set as part of the Sustainable Development Goals (SDG 3.3.2).

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**6. CONTACT INVESTIGATION COVERAGE**

Number of contacts of people with bacteriologically-confirmed TB who were evaluated for TB, divided by the number eligible, expressed as a percentage.

**Recommended Target Level:** ≥ 90%

**Main Rationale for Inclusion in Top-Ten:** Contact tracing is a key component of TB prevention, especially in children.
### 7. Drug Susceptibility Testing (DST) Coverage for TB Patients

Number of TB patients with DST results for at least rifampicin divided by the total number of notified (new and retreatment) cases in the same year, expressed as a percentage. DST coverage includes results from molecular (e.g. Xpert MTB/RIF) as well as conventional phenotypic DST results.

**Recommended Target Level:** 100%

**Main Rationale for Inclusion in Top-Ten:** Testing for drug susceptibility for WHO recommended drugs is essential to provide the right treatment for every person diagnosed with TB.

### 8. Treatment Coverage, New TB Drugs

Number of TB patients treated with regimens that include new (endorsed after 2010) TB drugs, divided by the number of notified patients eligible for treatment with new TB drugs, expressed as a percentage.

**Recommended Target Level:** ≥ 90%

**Main Rationale for Inclusion in Top-Ten:** An indicator that is relevant to monitoring the adoption of innovations in all countries. Indicators related to the development of new tools are needed at global level but are not appropriate for monitoring progress in all countries. The definition of which patients are eligible patients for treatment with new drugs may differ among countries.

### 9. Documentation of HIV Status Among TB Patients

Number of new and relapse TB patients offered HIV test divided by the number of new and relapse TB patients notified in the same year, expressed as a percentage.

**Recommended Target Level:** 100%

**Main Rationale for Inclusion in Top-Ten:** One of the core global indicators used to monitor collaborative TB/HIV activities. Documentation of HIV status is essential to provide the best care for HIV-positive TB patients, including ART.

### 10. Case Fatality Ratio (CFR)

Number of TB deaths (from a national VR system) divided by estimated number of incident cases in the same years, expressed as a percentage.

**Recommended Target Level:** ≤ 5%

**Main Rationale for Inclusion in Top-Ten:** This is a key indicator for monitoring progress towards 2020 and 2025 milestones. A CFR of 6% is required to achieve the 2025 global milestone for reductions in TB deaths and cases.
Progress towards global TB targets

WHO’s Global TB Report highlights that progress is off track and countries need to put in place urgent measures to restore access to essential TB services. The report further calls for a doubling of investments in TB research and innovation as well as concerted action across the health sector and others to address the social, environmental and economic determinants of TB and its consequences.

Data compiled by WHO’s Global TB Programme from all Member States and complemented by data from national surveys and databases managed by other WHO programmes and global agencies shows that:

The cumulative reduction in deaths between 2015 and 2021 was only 5.9 per cent, less than one-third to the milestone for 2020. The number of TB deaths is falling globally, but not fast enough to reach the first milestone of the End TB Strategy (a 35 per cent reduction from 2015 to 2020), and not fast enough to reach the target of a 90 per cent reduction in deaths by 2020.
Between 2018 and 2021, only 12.5 million people were provided TB preventive treatment. This is 42% of the target of 30 million for 2018-2022.

WHO recommends preventive treatment for people living with HIV and all contacts living in households with TB (including children under 5 years).

Between 2018 and 2021, only 12.5 million people were provided TB preventive treatment. This is 42% of the target of 30 million for 2018-2022.
Globally, the number of people newly diagnosed with TB and those reported to national governments dropped from 7.1 million in 2019 to 6.4 million in 2021. The combined total for 2018–2021 (26.3 million) was 66% of the way towards the 5-year target of 40 million for 2018-2022.

By 2022, US$ 13 billion is needed annually for TB prevention, diagnosis, treatment and care to achieve the global target agreed at the UN high level-meeting on TB in 2018.

Progress in the development of new TB diagnostics, drugs and vaccines, is constrained by the overall level of investment, which at US$ 1 billion in 2021 falls far short of the global target of US$ 2 billion per year.
THE 3 Pillars

The End TB Strategy encompasses a package of interventions that fall under three pillars.

The first Pillar – integrated patient-centred care and prevention - puts people living with TB at the heart of service delivery.

The second Pillar – bold policies and supportive systems – requires intense participation across government, communities and private stakeholders.

The third Pillar – intensified research and innovation - is critical to break the trajectory of the TB epidemic and reach the global targets.

The available guidelines, operational handbooks, toolkits and other resources in this compendium are organised within the different components under each of the Pillars to support country level implementation of the End TB Strategy.
INTEGRATED, PATIENT-CENTRED CARE AND PREVENTION

Early diagnosis of TB including universal drug-susceptibility testing, and systematic screening of contacts and high-risk groups

Treatment of all people with TB including drug-resistant TB, and patient support

Collaborative TB/HIV activities, and management of co-morbidities and TB-associated impairment and disability

Preventive treatment of persons at high risk, and vaccination against TB

BOLD POLICIES AND SUPPORTIVE SYSTEMS

Political commitment with adequate resources for TB care and prevention

Engagement of communities, civil society organizations, and public and private care providers

Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection control

Social protection, poverty alleviation add ‘other social determinants of TB’

INTENSIFIED RESEARCH AND INNOVATION

Discovery, development and rapid uptake of new tools, interventions and strategies

Research to optimize implementation and impact, and promote innovations

Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection control

Social protection, poverty alleviation add ‘other social determinants of TB’
The first pillar of the End TB Strategy focuses on achieving universal access to integrated patient-centred TB care and prevention, with special attention to vulnerable and hard-to-reach populations.

Early diagnosis of all cases, appropriate treatment for all people with any form of TB including all-oral shorter treatment regimens, and systematic screening of contacts and selected high-risk groups, as well as preventive treatment, are now an integral part of patient care and prevention.

Implementing patient-centred care in an integrated manner requires collaboration with other public health programmes such as human immunodeficiency virus (HIV), maternal and child health, nutritional care, diabetes care, lung health, impairments and disabilities, and mental health services, as well as with all relevant government and nongovernmental agencies, civil society, communities and the private sector.

In addition, the application of proven digital health tools is recommended to enhance the effectiveness of every aspect of TB care and prevention.
Patient-centred care involves systematically assessing and addressing the needs and values and preferences of patients and providing educational, emotional and economic support to enable them to complete the diagnostic process and the full course of prescribed treatment.

NTPs need to establish clear policies and strategies that incorporate social support into clinical care and deliver high-quality TB diagnosis and treatment to all patients—men, women and children, while preventing and managing TB-associated impairment and disability, without their incurring catastrophic costs. This calls for orientation and training of all health-care providers.

The following selected resources are currently available to support implementation of Pillar 1 of the End TB Strategy. The guidelines and corresponding handbooks are to be used primarily in national TB programmes, or their equivalents in Ministries of Health, and for other policy-makers and technical organizations working on TB and infectious diseases in public and private sectors and in the community.

Component 1A. Early diagnosis of TB including universal drug susceptibility testing, and systematic screening of contacts and high-risk groups

1A-1 Early diagnosis of TB including universal drug susceptibility testing

Rapid diagnostics for tuberculosis detection: WHO Consolidated Guidelines and Operational Handbook

The WHO consolidated guidelines on tuberculosis. Module 3: Diagnosis - Rapid diagnostics for tuberculosis detection 2021 provide critical guidance on the latest tools, innovations and steps to ensure that everyone can obtain a rapid and accurate diagnosis for TB, followed by treatment. Three new nucleic acid amplification test (NAAT) classes are endorsed by WHO and the consolidated guidelines provide background, justification and recommendations on these and earlier endorsed TB diagnostic technologies. This document is accompanied by the WHO operational handbook on tuberculosis. Module 3: Diagnosis - Rapid diagnostics for tuberculosis detection 2021 update, which aims at facilitating the implementation of the WHO recommendations by the Member States, technical partners, and others involved in managing patients with TB and DR-TB.
The “WHO consolidated guidelines on tuberculosis. Module 2: Screening – Systematic screening for tuberculosis disease” is a new consolidated policy guideline on tests for TB infection. The policy includes, for the first-time recommendations on a new class of Mycobacterium tuberculosis antigen-based skin tests (TBSTs) and consolidates all currently existing recommendations for the diagnosis of TB infection, including the traditional tuberculin skin test (TST) and interferon-gamma release assays (IGRAs). IGRAs and TBSTs use Mycobacterium tuberculosis complex specific antigens and represent a significant advancement to TST which has been used for over half a century.

The consolidated guideline provides background, justification, recommendations and implementation considerations on the WHO recommended TB infection tests. This document is accompanied by the “WHO operational handbook on tuberculosis. Module 3: Diagnosis – Tests for tuberculosis infection”, which provides laboratory personnel, clinicians as well as ministries of health and technical partners detailed guidance on how to implement the WHO evidence-based recommendations on TB infection tests. The document describes the WHO recommended tests, test procedures, a model algorithm, and the steps required to scale-up TB infection testing.

1A-2 Systematic screening of selected high-risk groups

Systematic screening for tuberculosis disease: WHO Consolidated Guidelines and Operational Handbook

The WHO consolidated guidelines on tuberculosis. Module 2: Screening – Systematic screening for tuberculosis disease consists of 17 new and updated recommendations which identify contacts of TB patients, people living with HIV, people exposed to silica, prisoners and other key populations who should be prioritized for TB screening. The new guidance also recommends different screening tools, namely symptom screening, chest radiography, computer-aided detection software, molecular WHO-approved rapid diagnostic tests, and C-reactive protein.

The recommendations are accompanied by a complementary operational handbook which provides practical advice on how to implement the WHO recommendations at the scale needed to achieve national and global impact. It is intended for all relevant personnel and stakeholders and aims to support policymakers and health professionals to choose the best approach to planning and implementing screening and active TB case-finding. It can support the development or updating of national guidelines for TB screening and will contribute to finding people with TB who may have been missed by the health system.

Component 1B. Treatment of all people with TB including drug-resistant TB, and patient support

To cure TB and reduce disease transmission, people living with TB should be placed on effective treatment soon after diagnosis. Treatment should be provided to all who need it regardless of age, sex, gender or type of TB disease, bacteriological status, co-morbidities or legal status. In most circumstances, community-based treatment support may lead to better adherence and more favourable outcomes. Ensuring all people living with TB have access to free-of-charge life-saving treatment is fundamental to minimizing disease and deaths.
Drug-resistant TB remains a public health crisis, and needs to be promptly and adequately addressed. WHO recommends shorter, fully-oral treatment regimens for people with drug-resistant TB, that can lead to better treatment outcomes.

**1B-1 Treatment of TB including drug-resistant TB among adults**

**Drug-Susceptible Tuberculosis Treatment: WHO Consolidated Guidelines and Operational Handbook**

Treatment of TB including drug-resistant TB among adults aims to inform national TB programmes, technical partners and other stakeholders about key findings and considerations on the use of the 4-month regimen for drug-susceptible TB following the assessment of new evidence. A review of evidence by WHO has shown similar performance of a shorter treatment regimen compared to the current standard regimen, both in terms of efficacy and safety. The 4-month regimen, which is shorter, effective and all-oral, would be preferable for many individuals and also national TB programmes, allowing faster cure and easing the burden on both people living with TB and the healthcare system. Shortened treatment has the potential to improve adherence and reduce health costs. Implementation and uptake of the new regimen in the short to medium term will be more feasible if the cost of rifapentine is reduced and availability improved.

**Drug-Resistant Tuberculosis Treatment: WHO Consolidated Guidelines and Operational Handbook, 2022 Update**

The WHO Consolidated Guidelines on Tuberculosis (TB), Module 4: Treatment - Drug-Resistant Tuberculosis Treatment 2022 update informs health care professionals in Member States on how to improve treatment and care for patients with drug-resistant TB (DR-TB). This document includes two new recommendations – one for the use of a 6-month BPaLM regimen, composed of bedaquiline, pretomanid, linezolid and moxifloxacin in patients with multidrug-resistant or rifampicin resistant TB (MDR/RR-TB) and those with additional resistance to fluoroquinolones (pre-XDR-TB) and another for a 9-month all oral regimen in patients with MDR/RR-TB and in whom resistance to fluoroquinolones has been excluded. In addition, the consolidated guidelines include existing recommendations on treatment regimens for isoniazid-resistant TB, longer all oral regimens, monitoring of treatment response, the timing of antiretroviral therapy (ART) in MDR/RR-TB patients infected with the human immunodeficiency virus (HIV) and the use of surgery for patients receiving MDR-TB treatment.

The WHO Consolidated Guidelines on Tuberculosis group all DR-TB recommendations in one document and are complemented by matching modules of the consolidated operational handbook.
Tuberculosis care and support: WHO Consolidated Guidelines and Operational Handbook

The WHO Consolidated Guidelines on Tuberculosis, Module 4: Treatment - Tuberculosis Care and Support informs health care professionals in Member States on how to improve treatment and care for patients with TB.

These guidelines group all recommendations on TB care and support in one document and are complemented by an operational handbook.

The guidelines are to be used primarily by national TB programmes, or their equivalents in Ministries of Health, stakeholders and technical organizations working on TB care in the public and private sectors and in the community.

The WHO Operational Handbook on Tuberculosis, Module 4: Treatment - Tuberculosis Care and Support provides practical guidance on how to put in place the recommendations at the scale needed to achieve national and global impact.

The document provides information on different aspects of care and support for TB patients. In particular, the handbook provides practical guidance on the implementation of the interventions that enable treatment adherence such as social support, treatment administration options, digital adherence technologies. The practical guidance also includes models of care for all TB patients, models of care for children and adolescents, integrated care for TB, HIV and comorbidities, engagement of private sector, managing of TB in health emergencies. This new practical handbook also includes two important chapters on health education and counselling, and palliative care for patients with TB.

Guidance for the surveillance of drug resistance in tuberculosis: Sixth edition

The aim of guidance for the surveillance of drug resistance in tuberculosis (April 2021) is to assist national tuberculosis programmes in developing the strongest possible mechanisms of surveillance for drug resistance in TB, building on more than 25 years of global experience. The guidance moves from periodic surveys of samples of people living with TB, towards the ultimate goal of continuous surveillance systems based on routine drug susceptibility testing. This guidance promotes certain standardized criteria for surveillance to ensure that results are comparable within and between countries over time. The target audience of this document is national TB programmes and, in particular, the coordination team for surveillance ideally composed of the programme manager, a laboratory specialist, a logistician, and an epidemiologist/statistician.

Position statement on innovative clinical trial design for development of new TB treatments

This position statement aims to support TB regimen development by highlighting key clinical trial characteristics to help advance novel therapies. It summarises key innovations in TB clinical trial designs, ranging from pharmacokinetic/pharmacodynamic modelling and new advances in biomarker development to the value of novel clinical trial design methodologies and post-licensure observational studies. For various stages along the development pathway, outstanding challenges are described alongside possible solutions to help overcome these issues. Beyond a welcome expansion of the TB drug pipeline, innovations in TB drug development and clinical trial design are anticipated to accelerate the development and evaluation as well as facilitate approval of novel regimens to treat all forms of TB.
The Roadmap: Towards ending tuberculosis in children and adolescents, outlines measures to prevent and treat TB in children and adolescents. It reflects the enhanced advocacy, increased commitment and joint efforts by all stakeholders to address the burden of TB among children.

Over 1 million children under the age of 15 years fall ill with TB every year and an estimated 67 million are infected with TB and are at risk of developing TB disease in the future. Despite significant progress and greater understanding of the challenges faced in addressing TB in children and adolescents, critical gaps remain in TB case detection and provision of TB preventive treatment in this group.

The Updated guidelines on the management of tuberculosis in children and adolescents incorporates new evidence and knowledge on the management of TB in children and adolescents. An accompanying operational handbook has been developed to facilitate implementation of the recommendations for improving care and outcomes for children and adolescents at risk of TB or with TB. It includes new recommendations on diagnostic options, treatment regimens, as well as treatment decision algorithms and optimal models of care for the delivery of child and adolescent TB services. It informs staff from ministries of health and care providers across public and private sectors, technical partners and other stakeholders about the key findings, considerations and changes related to the diagnosis, treatment and care of TB for children and adolescents.

The Roadmap: Towards ending tuberculosis in children and adolescents, outlines measures to prevent and treat TB in children and adolescents. It reflects the enhanced advocacy, increased commitment and joint efforts by all stakeholders to address the burden of TB among children.

Building on the first-ever Roadmap for Childhood TB: Toward Zero Deaths first issued in 2013, the new Roadmap towards ending TB in children and adolescents now includes recommendations on how to target young people aged between 10 and 19 years, who represent a significant at-risk group for TB. The Roadmap recommends 10 actions to improve TB services and save tens of thousands of children and adolescent lives from TB, including among those infected with both TB and HIV. The launch of the second roadmap on children, TB and adolescents combined with the United Nations General Assembly High-Level Meeting on TB present an important moment to consolidate and advance advocacy, commitment, resource mobilization and joint efforts by all stakeholders to address the burden of TB among children and adolescents.
Component 1C. Collaborative TB/HIV activities and management of co-morbidities

HIV is one of the major risk factors for TB, and TB is the leading cause of death among people with HIV. A significant reduction of TB incidence and elimination of HIV-associated TB deaths can be achieved by adopting and scaling up policies that ensure integrated, patient-centred prevention, early detection and treatment.

1C-1 Collaborative TB/HIV activities

WHO policy on collaborative TB/HIV activities

National policies to address HIV-associated TB can be adapted from the WHO policy on collaborative TB/HIV activities. These 2012 policy guidelines are a compilation of existing WHO recommendations on HIV-related TB. They follow the same framework as the 2004 interim policy document, structuring the activities under three distinct objectives: establishing and strengthening mechanisms for integrated delivery of TB and HIV services; reducing the burden of TB among people living with HIV and initiating early antiretroviral therapy; and reducing the burden of HIV among people with presumptive TB (that is, people with signs and symptoms of TB or with suspected TB and diagnosed TB).

Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach.

The guidelines bring in the most recent guidance on HIV testing strategies—the entry point for HIV prevention and treatment—and include comprehensive guidance on infant diagnosis. Key recommendations are presented on rapid antiretroviral therapy (ART) initiation and the use of dolutegravir. Updated recommendations are included on the timing of ART for people with TB, and the use of point-of-care technologies for treatment monitoring.

Differentiated approaches to HIV service delivery are emphasized, with several recommendations made to allow treatment to be started outside of the health facility and to reduce the frequency of contact with health services for people who are doing well on treatment. These recommendations help to ensure that people with HIV can start and continue treatment during times of service disruption as a consequence of the COVID-19 pandemic.
1C-2 Management of other co-morbidities

Framework for collaborative action on tuberculosis and comorbidities

Addressing comorbidities and risk factors for TB is a crucial component of Pillar one of the End TB Strategy, which focuses on integrated patient-centred care and prevention, including action on TB and comorbidities. The Framework for collaborative action on TB and comorbidities aims to support countries in the evidence-informed introduction and scale-up of holistic people-centred services for TB, comorbidities and health-related risk factors, with the goal of comprehensively addressing TB and other co-existing health conditions. It should be used in conjunction with relevant WHO guidelines. The Framework is intended for use by people working in ministries of health, other relevant line-ministries, policymakers, international technical and funding organizations, researchers, nongovernmental and civil society organizations, as well as primary care workers, specialist health practitioners, and community health workers who support the response to TB and comorbidities in both the public and private sectors.

WHO Disability policy: Since the inception of the End TB Strategy, piling evidence has increased on TB-associated impairment and disability. WHO and UN Agencies have developed policies to prevent impairment and disability.

The WHO Policy on Disability, launched by the Director-General on 3 December 2020, and accompanying action plans, serve as the primary framework for implementation of the United Nations Disability Inclusion Strategy (UNDIS) across the Organization.

Among others objectives, the WHO Policy on Disability requires WHO to integrate disability into the design, implementation, monitoring, and evaluation of all programmes, while continuing disability-specific or targeted initiatives for people with disability. The Global TB Programme is committed to work with stakeholders on the development of policies to address TB associated impairment and disability.
Component 1D. Preventive treatment of persons at high risk, and vaccination against TB

TB preventive treatment (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. In September 2018, at the first ever UNHLM on TB, all country leaders pledged to provide TPT to at least 30 million people at risk of TB disease between 2018 and 2022.

1D-1 Preventive treatment

Tuberculosis preventive treatment: WHO Consolidated Guidelines and Operational Handbook

The WHO consolidated TB guidelines will gradually group all TB recommendations and will be complemented by matching modules of a consolidated operational handbook. The 18 recommendations on tuberculosis preventive treatment in the 2020 update cover critical steps in programmatic management that follow the cascade of preventive care. The main changes introduced include conditional recommendations for a 1-month daily rifapentine and isoniazid regimen and a 4-month daily rifampicin regimen as alternative treatment options in all TB burden settings. Advice on isoniazid preventive treatment in pregnancy and on the concomitant use of rifapentine and dolutegravir has been updated to reflect the findings from latest studies. The operational limitations that need to be overcome by countries to achieve global targets are highlighted and will be discussed in greater detail in the accompanying operational handbook that is being released concurrently. The guidelines are to be used primarily in national TB and HIV programmes, or their equivalents in ministries of health, and for other policy-makers working on TB and HIV and infectious diseases in public and private sectors and in the community.

Call to Action 2.0: A global drive to scale up TB prevention

Call To Action 2.0: A global drive to scale up TB prevention, issued by WHO and its partners, urges governments and other stakeholders to keep the promises they made and accelerate coverage of TB preventive treatment for contacts of people with TB and others in need. Issued in May 2020, it points to the urgency of reaching 30 million people of all ages with TB preventive treatment · a commitment made by Heads of State at the UN High Level Meeting on TB in 2018. The Call follows the release of WHO guidelines in March 2020 to help countries accelerate efforts to stop people with TB infection becoming sick with TB by giving them preventive treatment. A quarter of the world’s population is estimated to have TB infection, and are at greater risk of developing TB disease, especially those with weakened immunity. Continuity of prevention and care for those affected by TB and other diseases is vital as countries put in place measures to contain the COVID-19 pandemic. This call to action emphasizes that countries, partners, donors and communities should work together to overcome the main barriers standing in the way of global scale-up in TB preventive treatment.
Target product profiles for tuberculosis preventive treatment

The aim of the target product profiles (TPPs) for tuberculosis preventive treatment is to identify the product attributes to be considered in developing the best, most suitable TB prevention treatments. These TPPs are expected to assist developers in aligning the characteristics of new treatment regimens and developers’ performance and operational targets with national requirements. This document describes priority and desirable regimen characteristics and outlines the minimal and optimal levels of acceptable performance for these attributes. In addition, it provides use case scenarios. The document is intended primarily for the pharmaceutical industry, academia, research institutions, product development partnerships, technical agencies, state and nongovernmental bodies, civil society organizations and donors.

Target product profile for next-generation tuberculosis drug-susceptibility testing at peripheral centres

In an effort to foster and achieve universal access to TB diagnostics and inform research and development priorities for TB diagnostic tools, WHO released (August 2021) an updated Target product profile (TPP) for next-generation tuberculosis drug-susceptibility testing for M. tuberculosis at peripheral centres.

This is one of the high-priority TPPs published by WHO for new TB diagnostics in light of several advances in the TB diagnostics and treatment pipelines that have been observed. This updated TPP is intended to specify desired attributes of next-generation drug-susceptibility testing for M. tuberculosis and align the development of new interventions with evolving gaps and the needs of individuals and populations. As the TB diagnostic pipeline evolves WHO will continue its efforts to regularly update this and other profiles.

An investment case for new tuberculosis vaccines

This document summarizes the results of the WHO-commissioned full value proposition for new tuberculosis (TB) vaccines. The assessment was commissioned to provide early evidence for national and global decision-makers involved in TB vaccine development and implementation, who include stakeholders involved in vaccine research, financing, regulation and policy-making, manufacturing, introduction and procurement. The goal is to accelerate development of effective vaccines against TB and their rapid introduction into countries.
WHO TB Knowledge Sharing Platform and E-Learning Platform

**TB Knowledge Sharing Platform**

The WHO TB Knowledge Sharing Platform provides access to a modular series of consolidated WHO TB guidelines, with corresponding operational handbooks and implementation aids. The guidelines and handbooks are accessible in pdf format as well as browser text. The content can also be customized according to user needs. The Platform is accessible via browser on a desktop or laptop as well as via mobile apps on Android and iOS stores.

**WHO’s End TB E-Learning Platform**

The e-learning platform provides access to the new WHO e-courses on TB preventive treatment, TB diagnostics and drug-resistant TB. These comprehensive, self-paced WHO developed e-learning materials have a programmatic focus and are designed for people providing guidance to stakeholders at country level in in developing and implementing the latest WHO guidelines and policy recommendations on TB, such as national programme managers and technical staff from ministries of health, WHO staff, staff of technical agencies, consultants and anyone else supporting countries and major subnational units.
PILLAR 2

BOLD POLICIES AND SUPPORTIVE SYSTEMS

The second pillar encompasses strategic actions within and beyond the health sector that will enable effective transformation and strengthening of policies and systems to support TB care and prevention. These actions include enhancing government stewardship and accountability, as well as pursuing TB-sensitive policies across government and systems to significantly improve access to needed health services, mitigate the social and economic consequences of TB, and act on its socioeconomic determinants as well as TB-associated impairments and disabilities.

The full implementation of the pillar requires action across the ministry of health with special roles for its national TB programme or equivalent, as well as by other ministries, nongovernmental partners and civil society. This needs to be linked to overall efforts to improve the financing, evidence-based policymaking and organization of health systems, as well as strengthening social and development policies. This work demands a multidisciplinary and multisectoral approach and therefore rests not only with the health ministry, but also with other ministries including finance, justice, labour, social welfare, housing, mining or agriculture.

Introduction
Component 2A. Political commitment with adequate resources for TB care and prevention

2A-1 Enhancing government stewardship

The End TB Strategy

The vision for the post-2015 global tuberculosis strategy is a world free of tuberculosis, also expressed as zero deaths, disease and suffering due to tuberculosis. The goal is to end the global tuberculosis epidemic.

Under this End TB Strategy, new, ambitious yet feasible global targets are proposed for 2030 and 2035 which could be realised, through optimizing the implementation of current tools and approaches, addressing social determinants of TB through universal health coverage and social protection, and investing in research and development sufficiently to develop and deploy new tools of elimination.

Moscow Declaration to End TB

The 2017 Moscow Declaration to End TB (5), was signed by 117 countries, affirming their commitment to end the TB epidemic by 2030 as envisaged in the Agenda 2030 for Sustainable Development and its SDGs, the WHO End TB Strategy, and the Stop TB Partnership Global Plan to End TB 2016-2020 (6).

Direction and commitment from the highest levels of government are essential to ensure action from across diverse ministries. Government stewardship needs to manifest itself in setting ambitious targets, driving cross-government engagement, enabling resource mobilization from domestic and international sources, overseeing implementation and monitoring progress.

Political declaration of the UN General-Assembly High-Level Meeting on the Fight Against Tuberculosis

Heads of State gathered in New York on 26 September 2018 at the United Nations General Assembly first-ever high-level meeting on tuberculosis (TB) to accelerate efforts in ending TB and reach all affected people with prevention and care. The theme of the meeting was “United to end tuberculosis: an urgent global response to a global epidemic” and culminated in the endorsement of an ambitious and powerful political declaration to accelerate progress towards End TB targets. This Political declaration of the UN General-Assembly High-Level Meeting on the Fight Against Tuberculosis was subsequently adopted by the General Assembly on 10 October 2018 as Resolution A/RES/73/3.

The high-level meeting on TB represents a tremendous and unprecedented step forward by governments and all partners engaged in the fight against TB.

It follows on from a very successful Ministerial Conference on Ending TB in Moscow in 2017 which resulted in high-level commitments from Ministers and other leaders from 120 countries to accelerate progress to end TB.
In 2018, the first DG Flagship Initiative was jointly launched with the Stop TB Partnership and the Global Fund titled “FIND. TREAT. ALL #ENDTB”. The initiative called for actions to rapidly close gaps and scale up access to care. Targets were set as part of the initiative to reach 40 million people with TB with care, and at least 30 million people with TB preventive treatment between 2018 and 2022. The targets from the initiative were used as the foundation for the targets and commitments made by Heads of State in the political declaration of the 2018 UN High Level Meeting on TB. Since 2018, the initiative has provided a strong political platform to urge countries to prioritize efforts to end TB, including through setting of country-specific targets, increased investments and high level advocacy through campaigns such as “Race to End TB”. However, countries have lagged behind in reaching the 2022 targets mainly due to the severe impact of the COVID-19 pandemic. An updated flagship initiative on ending TB under the leadership of WHO’s Director General is in the process of finalization for the period 2023-2027.

Regional Frameworks to end TB

Several WHO Regional Offices have developed region-specific frameworks to end TB at the request of and in consultation with the Member States. The frameworks are aligned with the global End TB Strategy and provide concepts for multisectoral actions that countries can adapt to their regional context and implement with all stakeholders to achieve the targets of the End TB Strategy. Examples of regional frameworks from the European, South-East Asian and Western Pacific WHO regions are highlighted here. The frameworks from the other three regions are currently under development and will be shared in the near future.

UN Secretary General Progress Report on TB: Progress towards achieving global tuberculosis targets and implementation of the UN Political Declaration on Tuberculosis

Published in 2020 this is a summary review of progress towards global TB targets and the implementation of the Political Declaration of the UN High Level Meeting on TB declaration in 2018. The report titled “Progress towards the achievement of global tuberculosis targets and implementation of the political declaration of the high-level meeting of the General Assembly on the fight against tuberculosis” was released by the United Nations Secretary-General António Guterres. While it acknowledged that high-level commitments and targets have galvanized global and national progress towards ending TB, it stressed that urgent and more ambitious investments and actions are required, especially in the context of the COVID-19 pandemic. The report was developed with the support of the WHO Director General, Dr. Tedros Adhanom Ghebreyesus and outlined 10 priority recommendations going forward. Member States are urged to implement the 10 priority recommendations to put the world on track to reach agreed targets by 2022 and beyond, and to reduce the enormous human and societal toll caused by TB.
As requested in the political declaration of the UN High Level Meeting on TB, a 2020 progress report was prepared by the UN Secretary-General, with support from WHO. The report included 10 priority recommendations.

- Fully activate high-level leadership to urgently reduce TB deaths and drive multisectoral action to end TB.
- Urgently increase funding for essential TB services including for the health workforce.
- Advance universal health coverage to ensure all people with TB have access to affordable quality care and resolve under-reporting challenges.
- Address the drug-resistant TB crisis to close persistent gaps in care.
- Dramatically scale up provision of TB preventive treatment.
- Promote human rights and combat stigma and discrimination.
- Ensure meaningful engagement of civil society, communities and people affected by TB.
- Substantially increase investments in TB research to drive technological breakthroughs and rapid uptake of innovations.
- Ensure that TB prevention and care are safeguarded in the context of COVID-19 and other emerging threats.
- Request WHO to continue to provide global leadership for the TB response, working in close collaboration with Member States and other stakeholders, including to prepare for a High-Level Meeting on TB in 2023.
An essential step in driving political commitment is wide stakeholder participation in developing or updating a national strategic plan with a clear vision of the 2030 and 2035 goals and targets to end TB, and the strategic actions required. WHO has developed a tool kit to assist countries in planning and programming.

The aim of the People-centred framework for TB programme planning and prioritization (2019) is to facilitate a systematic approach to country-led, data-driven and people-centred planning, prioritization and decision-making. The framework is most effectively applied during the development of a country’s National Strategic Plan (NSP). However, it can also be applied at other points in the country’s planning and policy cycle. The user guide outlines the concept of the framework and its possible applications, as well as case studies, data consolidation process and an organization of people-centred framework workshop. It is hoped that the framework will facilitate better use of the data to track the TB epidemic and progress in response efforts, at national and global levels. Major investments in national surveys, and improvements in surveillance and programmatic data, and other studies have increased the availability of quality data, the analysis of which is essential for national TB planning and prioritization.

Finally, the guidance is intended to be complementary to national planning processes. Where national guidance and tools for strategic planning are available, these should be used. This guidance and the accompanying tools serve as complementary resources for aspects of quality TB care and prevention that may not be optimally covered by existing national tools. This guidance will be published in 2022.

2A-2 Developing a comprehensive national TB strategic plan

An essential step in driving political commitment is wide stakeholder participation in developing or updating a national strategic plan with a clear vision of the 2030 and 2035 goals and targets to end TB, and the strategic actions required. WHO has developed a tool kit to assist countries in planning and programming.

The Guidance for National Strategic Planning for Tuberculosis supports strategic planning for TB, preferably conducted as part of the overall national health sector planning process.

This guidance may be used for developing standalone TB strategic plans, or to develop TB interventions as part of multi-disease or health sector strategic plans. The planning should be grounded on primary health care (PHC) and should contribute to universal health coverage (UHC) and address the broader determinants of health.

Additionally, this guidance promotes the development of NSPs that are human rights-based and that comprehensively address interrelated aspects of physical, mental and social health and wellbeing through inter-programmatic and multisectoral collaboration within and beyond the health sector. The interventions should put people at the centre, and provide comprehensive people-centred care, from promotion and prevention to treatment, rehabilitation and palliative care, without suffering financial hardships. Inclusive engagement of stakeholders, including TB affected communities and civil society, will facilitate planning for quality TB services that are responsive to the needs of people and affected communities and individuals, particularly those most affected by health disparities.

Finally, the guidance is intended to be complementary to national planning processes. Where national guidance and tools for strategic planning are available, these should be used. This guidance and the accompanying tools serve as complementary resources for aspects of quality TB care and prevention that may not be optimally covered by existing national tools. This guidance will be published in 2022.
The Multisectoral Accountability Framework (MAF-TB) was developed by WHO to support cross sectoral collaboration and accelerate progress, following the November 2017 Moscow Declaration to End TB and the political declaration of the 2018 UNHLM on TB. The rationale for such a framework is that strengthened accountability for the response to tuberculosis at national and global levels should contribute to faster progress towards the targets and milestones of the End TB Strategy.

The MAF-TB aims to strengthen accountability by Member States, as well as multisectoral partners and stakeholders, at national, regional and global levels in order to accelerate progress to end the TB epidemic by 2030, including the meeting of commitments and targets set for 2022 and 2030.

This Compendium of data and evidence-related tools for use in TB planning and programming (2021) is designed to help NTPs to make best use of the available tools for policy, planning and programmatic action. The document summarizes information about the key tools related to data and evidence that are available for use in TB planning and programming, and how they can be applied. The tools that are profiled are described in terms of how they fit within the People-centred framework for tuberculosis programme planning and prioritization.

Together with the people-centred framework, this compendium aims to enable better use of data and evidence for TB programme planning at both the national and subnational levels.

2A-3 Multisectoral Accountability Framework (MAF-TB)

The Multisectoral Accountability Framework (MAF-TB) was developed by WHO to support cross sectoral collaboration and accelerate progress, following the November 2017 Moscow Declaration to End TB and the political declaration of the 2018 UNHLM on TB. The rationale for such a framework is that strengthened accountability for the response to tuberculosis at national and global levels should contribute to faster progress towards the targets and milestones of the End TB Strategy.

Multisectoral accountability framework to accelerate progress to end tuberculosis by 2030

- The MAF-TB aims to strengthen accountability by Member States, as well as multisectoral partners and stakeholders, at national, regional and global levels in order to accelerate progress to end the TB epidemic by 2030, including the meeting of commitments and targets set for 2022 and 2030.

- The MAF-TB helps identify who is accountable, what they are accountable for, and how they will be held accountable, at country and local levels, as well as at regional and global levels.

- The four essential components of the MAF-TB are shown below in a cycle. These components are consistent with frameworks and measures in many other fields across sectors.

- The MAF-TB has two parts: one focused on accountability at national (including local) level; and the other on accountability at global and regional levels, which applies to countries collectively. There are four critical components of accountability at all levels: commitments, actions, monitoring and reporting, and review.
The four essential components of the Multisectoral Accountability Framework -TB

MAF-TB baseline assessment checklist

To support efforts in adaptation and use of MAF-TB at country level, WHO developed a baseline assessment checklist (8). This can be used to assess the status of core elements of the MAF-TB and to inform related efforts, including stakeholder consultations to develop national MAFs, NTP reviews, updating of national strategic plans and civil society audits. Importantly, it includes an annex on engagement of civil society and affected communities that was developed jointly with the WHO Civil Society Task Force (9) which is helping advocate and support the application of the MAF-TB at national level. Civil society have been closely engaged at global, regional and national levels to strengthen accountability.
Operational Guidance on adaptation and implementation of the World Health Organization Multisectoral Accountability Framework to end TB (MAF-TB)

The Operational Guidance on adaptation and implementation of the World Health Organization Multisectoral Accountability Framework to end TB (MAF-TB) aims to facilitate and promote the adaptation and implementation of MAF-TB at national (and local) levels. The objectives of the Guidance are to provide practical advice on key approaches to establishing MAF-TB at national (and local) levels; share concrete examples, best practices and case studies of MAF-TB adaptation and use at national and local levels, and encourage political leaders, policymakers within and beyond the health sector, civil society and affected communities, international partners, and funders to join forces in efforts to end TB. The Guidance helps to ensure that all stakeholders have a shared understanding of what values and theoretical constructs inform the course of action across all four components as well as what indicators and mechanisms should be in place to monitor and review progress.

Best practices in the adaptation and implementation of WHO’s multisectoral accountability framework for tuberculosis (MAF-TB)

This document includes case studies from all six WHO regions. It provides important, valuable insight into how regions and countries are progressing with its implementation and what has been learnt along the way. All case studies provide concrete, tangible examples of MAF-TB adaptation and implementation related to one or more of the MAF-TB essential components, as well as the process of organizing and conducting a MAF-TB Baseline Assessment using the WHO Checklist and Annexes. This compilation of best practices also serves as an inspiration for those involved in TB control in one form or another, and fuels further progress in ending the TB epidemic. The document will also inform preparation for a comprehensive review by Heads of State and Government for the next UNHLM on TB in 2023.
Component 2B.
Engagement of communities, civil society organizations, and all public and private care providers

Engaging communities, civil society organizations and all public and private care providers is critical to global efforts to End TB. Informed community members can identify people with suspected tuberculosis, refer them for diagnosis, provide support during treatment and help to alleviate stigmatization and discrimination. Civil society organizations have specific capacities and tuberculosis programmes can benefit from harnessing them to widen the network of facilities engaged in TB care and prevention as well as policy development and planning.

Scaling up public–private mix approaches will help ensure people living with TB are not “missed” and that all TB prevention and care providers, whether public or private adhere to responsive, people-centred, rights-based and equitable strategies.

2B-1 Engaging communities and civil society organizations

WHO Civil Society Task Force on TB: engagement with civil society as a driver for change:
Progress report, March 2020 - June 2021

The WHO Civil Society Task Force on TB is a platform for discussion and exchange with WHO with emphasis on harnessing the untapped potential in engagement with civil society and affected communities at global, regional and country levels.

The latest report of WHO’s Civil Society Task Force on TB: an overview of progress and achievements in 2020 and 2021 in the areas of high-level engagement and advocacy, UN Secretary-General’s priority recommendations and Task Force action, impact in high TB burden countries, boosting multisectoral accountability, engagement in WHO guideline development process, and others.

Joint Statement: Call for increased political commitment and accountability in preparation for the 2023 United Nations High-Level meeting on Tuberculosis

In June 2022, WHO’s Director-General Dr Tedros Adhanom Ghebreyesus held a dialogue with WHO’s Civil Society Task Force on Tuberculosis (CSTF-TB) in Geneva, Switzerland. The dialogue was followed by an online town hall with civil society and affected communities on priorities for the CSTF-TB and its engagement with the broader civil society and affected communities working on TB.

Recognizing the importance of the 2023 United Nations General Assembly High-level Meeting on TB (2023 UNHLM on TB) in fostering high-level political will, enhancing collaboration, mobilizing resources for people-centered services for TB-affected individuals, households and communities, CSTF-TB requested WHO to take the lead in leveraging the multistakeholder taskforce to set collective priorities in preparations for the 2023 UNHLM on TB.
2B-2 Engagement of all public and private care providers

Public–private mix for TB prevention and care: a roadmap

The Public–private mix for TB prevention and care: a roadmap, was produced in 2018 to help ensure that millions of people with TB are not “missed” by the national TB programmes, and that the TB treatment and care from public and private providers not engaged by the NTP, is patient-centred, quality-assured and affordable.

WHO and global partners launched the roadmap to scale up the engagement of public and private health care providers in efforts to end TB. It builds on a landscape analysis of the private health sector on TB and identifies clear actions needed to expand the engagement of all care providers towards universal access to care.

Since 2001, WHO and its partners have offered support on engaging private providers for TB prevention and care, the need for which has been recognized in global TB strategies since 2006. Since 2002, the Public Private Mix Working Group of the Stop TB Partnership has held 15 global meetings on public and private sector providers, several WHO guidance documents have been issued and a number of major reviews of the literature have been published.

Engaging private health care providers in TB care and prevention: a landscape analysis - Second edition

An essential premise of Engaging private health care providers in TB care and prevention: a landscape analysis is that global and national goals in TB cannot be achieved unless private providers are engaged on a scale commensurate with their role in health systems.

The investments in scaling up public-private mix approaches do not currently meet the real needs on the ground. Some countries have made more sustained progress than others, however, overall engagement of private providers remains weak considering the important role of private providers in many high-burden countries.

The purpose of this publication is to facilitate improved engagement of private providers, thereby contributing to universal access to quality and affordable TB care and the end of the TB epidemic. It focuses on the role of private for-profit providers and on specific challenges and experiences in engaging them for TB prevention and care.

2B-3 Mobilizing youth to end TB

Youth engagement

Young people are drivers of social progress. Historically, they have inspired the world with their vision for social justice. Youth can have a multiplier effect in the fight to end TB, to accelerate progress towards reaching the ambitious 2022 targets of the UN High Level Meeting on TB, as well as the larger goal of ending TB by 2030.
Youth declaration to end TB

In 2019, young people from across the globe came together and pledged their commitment to end tuberculosis at the first-ever Youth Town Hall to End TB in Jakarta, Indonesia. Through a bold Youth Declaration on the Fight to End TB, youth representatives, including from high TB burden countries such as Bangladesh, India, Indonesia, Kenya and the Philippines, outlined key commitments and actions they would lead to accelerate efforts to end TB.

WHO 1+1 Initiative

WHO has launched an initiative called “1+1” to promote stronger engagement with young people, enabling them to amplify their voices to end TB. The “1+1” initiative relies on small actions at which young people can excel. By utilizing the untapped resource of youth, the world can benefit from a social multiplier effect. If each one (youth) reaches one (youth), millions will be reached and momentum achieved to end the TB epidemic. Over 30,000 young people have been meaningfully engaged in WHO’s 1+1 Initiative since its inception.
Universal health coverage for TB will be achieved by expanding access to the full range of high-quality TB services, and expanding coverage of all expenditures associated with TB prevention and care, for all those in need.

Regulatory frameworks must be strengthened and enforced, especially in countries with a high tuberculosis burden, including mandatory notification of tuberculosis cases without which disease surveillance will be severely hampered. Accurate registration of TB deaths will ensure accurate reporting of the disease – and the production, quality and use of tuberculosis diagnostics and medicines must be regulated to ensure quality treatment, good outcomes and less chance of drug resistance developing. Effective infection control in health care and other settings should be part of infectious disease legislation.

**Tuberculosis patient cost surveys: a handbook**

This handbook builds on lessons learned from surveys implemented 2015-2017 and advice provided by the Global task force on cost surveys of people living with TB. It provides a standardized methodology for conducting health facility-based cross-sectional surveys to assess the direct and indirect costs incurred by people living with TB and their households. In addition, it provides recommendations on results dissemination, engaging across sectors in policy dialogue and enabling action and related research for effective modifications in care delivery models, and support for people living with TB, and wider cross-sectoral interventions.

To inform policy and practices for improved social protection of people living with TB and affected households, and to reach the 2020 End TB Strategy target that no person or household should face “catastrophic total costs” due to TB, WHO is supporting countries to design, implement, analyze and translate into policy recommendations TB patient cost surveys.

**WHO guidelines on tuberculosis infection prevention and control - 2019 Update**

These guidelines provide updated, evidence-informed recommendations on TB infection prevention and control (IPC) in the context of the global targets of the SDGs and the WHO End TB Strategy. The notion and practice of IPC encompasses a set of broader, practical, evidence-based approaches to prevent the community from being harmed by avoidable infections, prevent health care-associated infections, implement laboratory biosafety and reduce the spread of antimicrobial resistance. The IPC refers to a group of interventions aimed at minimizing the risk of Mycobacterium tuberculosis transmission in health care and other settings. The recommendations replicate those described in earlier WHO guidelines but focus on the spectrum of measures as a “package” of interventions. These updated guidelines continue to emphasize the need to implement the hierarchy of infection control as a systematic and complex approach for strengthening IPC and reducing the risk of TB transmission.
Global Tuberculosis Report 2022

Each year, the WHO Global TB Report provides a comprehensive and up-to-date assessment of the TB epidemic, and of progress in prevention, diagnosis and treatment of the disease, at global, regional and country levels. This is done in the context of global TB commitments, strategies and targets. In 2022, 202 countries and territories with >99% of the world’s population and TB cases reported data.

A top message from the 2022 Report is the impact of the COVID-19 pandemic which has reversed years of progress in providing essential TB services and reducing TB disease burden. Global TB targets are mostly off-track, although there are some country and regional success stories. The most obvious impact is a large global drop in the number of people newly diagnosed with TB and reported. This fell from 7.1 million in 2019 to 6.4 million in 2021. Reduced access to TB diagnosis and treatment has resulted in an increase in TB deaths.

Actions to mitigate and reverse these impacts are urgently required. The immediate priority is to restore access to and provision of essential TB services such that levels of TB case detection and treatment can recover to at least 2019 levels, especially in the most badly-affected countries.

Report App

This app was created by the World Health Organization (WHO) to allow users to explore and interact with the data from the WHO 2022 Global Tuberculosis Report.

FEATURES

- Key facts on the tuberculosis epidemic
- Data from 200+ countries and areas
- Visualize statistics and trends for national, regional and global levels
- Customize your own groups by selecting up to 30 countries. The app will calculate values for key indicators
- Compare countries, regions or your custom groups
- Quick search of indicators
- Works offline – always have access to the data
- Always free – public data compiled by WHO
- Available in English, French, Russian and Spanish – switch between the four at any time

iOS: link  Android: link
Component 2D.
Social protection, poverty alleviation and actions on other determinants of TB

Even when tuberculosis diagnosis and treatment are offered free of charge, social protection measures are needed to alleviate the burden of income loss and non-medical costs, for TB prevention purposes by addressing the social determinants of TB and finally for the mitigation of the impact of TB-related disabilities. Expanding social protection (coverage), as well as addressing the social determinants of TB and pursuing a ‘health in all policies’ approach needs to be undertaken to enhance TB prevention and reduce the physical, financial and social burden of TB, including TB-associated impairments and disabilities, impoverishment, stigmatization, isolation and discrimination, school abandonment and learning impairment, loss of employment and divorce.

Costing Guidelines for Tuberculosis Interventions

Estimating the cost of TB interventions is essential for planning, prioritizing and managing the funding of TB services. Costing guidelines for TB Interventions (2019) explains how to cost TB interventions from the perspective of the providers of health services. The costs are those incurred by a hospital, clinic or TB facility providing the services. Tools for data collection, referred to as the Value TB Costing Tool Suite, are included.

The guidelines build on and update those previously published by WHO and are consistent with the Global Health Costing Consortium’s Reference Case for Estimating the Costs of Global Health Services and Interventions which provides a set of standardized principles and methods for collecting and evaluating cost data from a provider perspective (as opposed to that of a patient or household).

These guidelines also complement WHO guidance on estimating costs borne by TB-affected households.
Tuberculosis (TB) remains one of the leading infectious diseases causing millions to fall ill and lose their lives annually. Refugees and other populations in humanitarian settings face substantial threats to health and survival, such as poverty, crowded living conditions, undernutrition and poor access to health services – all conditions in which TB transmission thrives.

This guide is a joint effort of the Centers for Disease Control and Prevention (CDC), the UN High Commissioner for Refugees (UNHCR) and the World Health Organization (WHO). It includes new strategic approaches, guidance and innovations for TB prevention and care interventions in humanitarian settings. The guide focuses primarily on managerial/organizational aspects of TB interventions, and provides links to the most updated references for the clinical aspects. We hope this guide can serve as a useful tool in humanitarian settings to alleviate the suffering and deaths caused by this preventable and curable disease, especially for refugees and displaced populations in humanitarian settings.

WHO information note on ensuring continuity of essential tuberculosis services for people with or at risk of the disease within Ukraine and in refugee-hosting countries

The World Health Organization (WHO) is working closely with Ukraine, countries hosting refugees, affected populations and partners to rapidly respond to the humanitarian crisis caused by war and minimize disruptions to the delivery of critical health care services. As part of these overarching efforts, WHO is working to enable access to tuberculosis (TB) care services for all people with or at risk of TB within Ukraine and in refugee-hosting countries.

A special information note has been released by WHO providing key information and guidance on ensuring continuity of essential TB services for people with TB and refugees affected by the war in Ukraine. This note provides an overview of key tools available to health authorities, partners, civil society and other stakeholders. WHO continues to monitor the situation closely for any changes that may influence this note and will issue updates should any factors change.
PILLAR 3

INTENSIFIED RESEARCH AND INNOVATION

Introduction

The third pillar of the End TB Strategy – research and innovation – recognizes that achieving substantial reductions in TB incidence and mortality will require the development and introduction of new tools and strategies, in addition to promoting universal access to existing technologies.

In this regard, Ministers of Health during the first Global Ministerial Conference on Ending TB in Moscow, 2017, committed to take necessary actions to catalyse TB research, particularly by increasing investment for health research, reducing regulatory impediments and enhancing in-country TB research capacity. The Political declaration of the UN high-level meeting of the General Assembly on the fight against TB, also articulated bold commitments and actions on TB research and innovation. Translation of these commitments into action will require a coherent and integrated approach at the national, regional and global levels.
Component 3A. Discovery, development and rapid uptake of new tools, interventions and strategies

Since 2007, several new tests and diagnostic approaches have been endorsed by WHO, but an accurate and rapid point-of-care test that is usable in field conditions is still missing. The pipeline of new drugs has expanded substantially over the last decade, but even greater investments are required in both research and capacity building to implement trials in accordance with international standards.

Diagnostic tests and treatment strategies to identify latent TB and prevent its development are also needed, as is an effective vaccine to replace the century-old BCG vaccine. Currently there are 12 vaccine candidates in clinical trials. More research and investments are required to address major scientific challenges and identify priorities for future tuberculosis vaccine research. A post-exposure vaccine that prevents the disease in latently infected individuals will be essential to eliminate tuberculosis in the foreseeable future.

A Global Strategy for tuberculosis research and innovation

The global strategy for TB research and innovation, was developed through broad global consultation within and without the TB research and innovation community. This strategy aims to provide countries with a framework to facilitate the implementation of the commitments on research and innovation articulated in declarations by Ministers of Health during the first Global Ministerial Conference on Ending TB (November 2017, Moscow), and in the Political declaration of the UN high-level meeting of the General Assembly on the fight against TB.

Four major areas for action are highlighted in the strategy: creating an enabling environment for TB research and innovation; increasing financial investments in TB research and innovation; promoting and improving approaches to data sharing; and promoting equitable access to the benefits of research and innovation. A prerequisite for success is that all stakeholders make concerted efforts and collaborate. The strategy makes the case for a unified and aligned response in which key national and international partners and affected communities support Member States by undertaking the investments and partnerships that are necessary for accelerating innovation. The primary audiences for the document are Member States, particularly ministries of health, science and technology, finance and education.

Framework for the evaluation of new tests for tuberculosis infection

The Framework for the evaluation of new tests for TB infection aims to promote and direct research by identifying standard study designs and evaluation protocols. As such it should facilitate their standardized evaluation and accelerate adoption into global and national policy and subsequent scale-up.

The framework provides guidance on study design, populations, reference standards, sample size calculation and data analysis. Additionally, it covers technical issues that should be considered when evaluating new tests for TB infection, evaluation of safety for skin tests, costs to the health system patients, preferred features and operational characteristics.

The document is intended for test manufacturers, researchers, research funders, regulators, TB programme coordinators, civil society and other stakeholders.
Component 3B. Research to optimize implementation and impact and promote innovation

Research aimed at developing interventions that result in improved policies, better design and implementation of health systems and more efficient methods of TB service delivery, is critical.

Research is also needed to identify and address bottlenecks to implementation of existing and new policies, and to provide evidence from the perspective of patients as well as from health systems.

Good systems for research prioritization, planning and implementation need to be in place at country level and research-enabling environments need to be created to foster better and more relevant operational, health system and social science research that will help implementation.

Implementation Research for Digital Technologies and TB

Digital technologies have significant potential to advance progress towards End TB targets and are increasingly used as a tool for TB programmes in low and middle-income countries. Digital technologies are being applied in varied and innovative ways to help overcome some of the key challenges and barriers that limit efforts for prevention, detection, treatment and management of TB, such as digital tools to promote treatment adherence, support learning and knowledge dissemination, and improve the quality, accessibility, and sharing of TB programme data.

The Implementation Research for Digital Technologies and TB toolkit (IR4DTB) has been designed for TB programme implementers (middle and senior-level managers) and other decision makers who are interested in trialling, or currently implementing, digital technology tools and are seeking guidance on how to conduct implementation research to evaluate the implementation and scale up of digital technologies within TB programmes. The toolkit is organised into six modules that guide users through conceptualising, budgeting, and preparing for an implementation research study. The activities and examples contained within this toolkit have been designed to facilitate the development of a comprehensive implementation research proposal that can be used to support fundraising efforts for future research.

Situational assessment checklist to guide implementation of the global strategy for tuberculosis research and innovation

The Situational assessment checklist to guide implementation of the global strategy for tuberculosis research and innovation allows for a robust analysis of the current situation at country level, to build an evidence base for prioritizing the implementations of the recommendations made in the global strategy for tuberculosis research and innovation through changes in policies, programmes and interventions. It is designed as a reference for ministries of health and other entities responsible for overseeing the implementation of the global strategy for TB research and innovation.
Drug resistance must be detected rapidly and accurately to initiate appropriate and effective treatment.

The detection of TB resistant to the treatment rifampicin (RIF) has improved significantly in the past decade with the introduction of rapid diagnostic tools based on DNA detection. The introduction of these tools has dramatically elevated the number of people tested for RIF resistance, leading to a 129% increase in the number of individuals started on second-line TB treatment between 2012 and 2019.

The majority of people with RIF-resistant TB can be detected by analysing the 81-base pair fragment of the rpoB gene region. However, the situation is not that clear for other anti-TB drugs due to the lack of knowledge of how phenotypic resistance is associated with mutations in the Mycobacterium tuberculosis genome.

In response to this issue the WHO has developed a Catalogue of mutations in Mycobacterium tuberculosis complex and their association with drug resistance. The catalogue provides a reference standard for the interpretation of mutations conferring resistance to all first-line and a variety of second-line drugs. The catalogue lists over 17000 mutations, their frequency and association with or not with resistance and includes methods used, mutations identified and summaries of important findings for each drug.

Tuberculosis laboratories around the world can use the catalogue as a support in the interpretation of genome sequencing results. The catalogue can also guide the development of new molecular drug susceptibility tests, including next-generation sequencing.
TB GUIDANCE IN THE CONTEXT OF COVID-19

PART FOUR
Introduction

In 2020, COVID-19 derailed the global economy and halted and reversed global progress in health and development. TB care and prevention has been particularly affected as human, financial and other resources were redirected to the COVID-19 response, and the global implementation of public health measures resulted in reduced access to TB diagnosis and treatment services, as well as considerable impoverishment of already TB-vulnerable populations.

For the first time in nearly two decades, WHO reported an increase in the number of people falling ill with TB and drug resistant TB in 2021, alongside an increase in deaths.

The pandemic has highlighted the critical need to maintain essential quality health services during emergencies and the need for robust national strategic plans which ensure the country level response can cope with changing contexts.

Importantly, the pandemic has also highlighted the interlinkages between TB and COVID-19. Given the similar disease presentation, WHO/GTB is promoting knowledge sharing and research on the interlinkages to support the timely response to the dual threat of COVID-19 and TB.

The following tools have been developed across all three Pillars of the END TB Strategy to address TB and COVID-19.
WHO Information Note: COVID-19 considerations for tuberculosis care

In April 2020 the WHO/ GTB Programme, along with WHO regional and country offices, issued an urgent Information Note, Considerations for tuberculosis (TB) care in collaboration with stakeholders, to assist national TB programmes and health personnel in their efforts to maintain continuity of essential services for people affected with TB during the COVID-19 pandemic.

The information note highlights innovative people-centred approaches, and emphasizes the collaboration and joint support that will be essential in tackling both diseases. It stresses the need to protect the progress that has been made in TB prevention and care, and ensure it is not reversed by the COVID-19 pandemic. Finding and treating people with TB remains fundamental to TB prevention and care. The updated note has additional details on clinical management considerations for TB and COVID-19, as well as new information on testing.

Programmatic innovations to address challenges in tuberculosis prevention and care during the COVID-19 pandemic

New knowledge and lessons from successful programmatic innovations are urgently needed to improve TB prevention and care and avoid a reversal of progress from the adverse impacts of the COVID-19 pandemic. Experience can provide evidence for innovative approaches and strategies to maintain and scale up high-quality TB services. Programmatic innovations that address emerging challenges in TB prevention and care during the pandemic is a collection of 23 selected case studies submitted by 19 countries across the six regions of WHO between November 2020 and February 2021. The lessons learnt from these country innovations may also inform strategies for minimizing the impact of future emerging pathogens on health services.

Ensuring continuity of TB services during the COVID-19 pandemic (May 2021)

This updated information note, Ensuring continuity of TB services during the COVID-19 pandemic: COVID-19 considerations for tuberculosis care (May 2021), is intended to assist national TB programmes and health personnel worldwide to maintain essential TB services during the COVID-19 pandemic and in the recovery phase. It emphasizes the importance of protecting the recent progress made in TB prevention and care. WHO/GTB, along with WHO regional and country offices, developed this note in response to questions received from Member States and other partners since the start of the pandemic. The note includes references to other published WHO information products relevant to TB practitioners. This information note was originally published on 20 March 2020 and later updated on 4 April, 12 May, 15 December in 2020, and 5 May in 2021.
Compendium of TB/COVID-19 studies

This compendium of key resources is to facilitate knowledge sharing and promote research on the interlinkages between TB and COVID-19. Given similar disease presentation between TB and COVID-19, and the adverse impact of this pandemic on TB services and health outcomes, knowledge sharing is important for a timely response to both diseases.

As a resource for implementers, researchers, funders, civil society and policy makers to build on lessons learned and strengthen preparedness to mitigate the impact of outbreaks like COVID-19 on the millions ill with TB as well as national TB programmes, the compendium presents a clear overview of the TB/COVID-19 research landscape, enabling researchers and funding institutions to better prioritize and deploy their time and resources.

The Compendium of TB/COVID-19 studies includes the following resources:

<table>
<thead>
<tr>
<th>Case studies focusing on programmatic innovations in TB prevention and care, in the context of the COVID-19 pandemic</th>
<th>Compendium of ongoing TB/COVID-19 research projects</th>
<th>Digital library of TB/COVID-19 publications</th>
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<td>This ongoing initiative seeks to collect lessons learnt from countries and partners on innovative solutions being implemented to address programmatic barriers in the clinical, social and economic management of TB disease, created or exacerbated by the COVID-19 pandemic. It envisions to communicate high quality case studies on WHO’s website to allow learning from the implementing countries.</td>
<td>provides a listing of ongoing research activities at the interface of TB and COVID-19, self-reported by research investigators from different countries. It maps multi-country efforts in the development of evidence for the co-management of TB and COVID-19, with a view to stimulate cooperation between scientists, funding institutions, policy makers, and civil society. The compendium also includes clinical trials on BCG vaccine testing against COVID-19.</td>
<td>These resources will remain living documents that will be updated regularly to facilitate knowledge sharing and collaboration.</td>
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Looking Ahead
UN Secretary General’s Priority Recommendations

PART FIVE
There is an urgent need to redouble efforts and accelerate the TB response to get back on track towards reaching the End TB targets. To reverse the impact of the pandemic, avert preventable deaths and put the world on track to end TB, essential TB services must be restored rapidly, and more domestic and international resources need to be mobilized. The development and uptake of new technologies and innovative integrated care approaches must improve. As requested in the 2020 report of the United Nations Secretary-General to the General Assembly, WHO will continue to provide global leadership for the TB response, working in close collaboration with all stakeholders, including to prepare for a high-level meeting on TB in 2023. Member States are urged to implement the following 10 priority recommendations to put the world on track to reach agreed targets by 2022 and beyond, and reduce the enormous human and societal toll caused by TB.
10 PRIORITY RECOMMENDATIONS
UN Secretary-General Progress Report on ending TB

1. Fully activate high-level leadership to urgently reduce TB deaths and drive multisectoral action to end TB

Given that TB is the world’s top infectious killer, that it is a preventable and curable disease, that progress is too slow to reach global targets; and that TB incidence is declining far too slowly, the key drivers of the TB epidemic include social and economic determinants such as poverty and under-nutrition as well as health-related risk factors, that half of people with TB and their households face catastrophic costs; and that the COVID-19 pandemic poses a major risk that TB deaths, TB incidence and the number of people with TB facing catastrophic costs will significantly increase. Ensure that high-level multisectoral collaboration and accountability under the leadership of Heads of State or Government, including regular reviews of progress, is in place in all countries - especially those with a high TB burden. Ensure that progress towards national targets for reductions in TB deaths and TB incidence is regularly monitored and reviewed at the highest level, and findings acted upon, especially in countries with a high burden of TB. Strengthen national notification and vital registration systems so that they meet quality and coverage standards, to ensure robust measurement of trends in TB incidence and deaths. Ensure social protection measures including essential benefit packages and subsidization schemes are fit-for-purpose, so that no one affected by TB faces catastrophic costs.

2. Urgently increase funding for essential TB services including for the health workforce

Given that funding for universal access to TB prevention, diagnosis, treatment and care is vital to achieve a substantial reduction in TB deaths, that funding needs to double to reach the global target of at least US$ 13 billion per year by 2022 and that spending on TB offers one of the best returns on investment in health and development: Increase domestic funding to combat TB, especially in middle-income countries with a high TB burden, while also building synergies in the response to both TB and COVID-19. Increase international donor funding for the TB response, from both existing or new innovative funding mechanisms, so that funding levels are commensurate with the burden of disease.
Given that Member States have committed to reach an additional one billion people with essential health services by 2023, that access to TB treatment is increasing but not yet enough to reach the target of 40 million between 2018 and 2022, and that there is an annual gap of about 3 million people, including half a million children, who miss out on access to care or are not reported: Ensure that TB services are maintained and strengthened as an essential component of sustainable health systems and progress towards universal health coverage. This includes as recommended by WHO, expanded access to: - rapid molecular diagnostics as the initial test to diagnose TB including resistance to key drugs - treatment with new effective drugs and regimens - psychosocial, nutritional and other support -systematic screening for TB and TB preventive treatment Improve financial protection for people affected by TB and drug resistant TB through relevant mechanisms, such as national health insurance systems or other pooled pre-payment schemes, across public and private health sectors. Scale up engagement and leverage the capacity of private and other unlinked public health care providers in the delivery of TB prevention, diagnosis and care services to reach the missing people with TB including children, especially in countries with a large private sector. Ensure mandatory notification of all people diagnosed with TB, covering public, private and community-based providers, facilitated by expanded use of electronic case-based reporting and digital technologies.

Given that drug-resistant TB is a major contributor to antimicrobial resistance and is a threat to global health security; that close to half a million people develop drug-resistant TB every year, of which less than half are diagnosed and only around 100 000 successfully treated; and that progress towards the target of treating 1.5 million people with drug-resistant TB including 115 000 children between 2018 and 2022 is therefore far too slow. Expand use of rapid molecular TB diagnostics and test all those diagnosed with TB and rifampicin resistance for susceptibility to the fluoroquinolone class of drugs. Expand access to WHO-recommended all-oral treatments for adults and children diagnosed with drug-resistant TB. Increase access to affordable high-quality drugs and diagnostics for populations in need, using effective mechanisms such as the Stop TB Partnership Global Drug Facility. Include actions to address drug-resistant TB explicitly within national antimicrobial resistance strategies and plans.
Given that access to TB preventive treatment is increasing far too slowly to reach the target of 30 million people between 2018 and 2022, due to very low coverage among household contacts of people diagnosed with TB:

Massively expand household contact investigation including for children and people with drug-resistant TB, by updating national policies and strategies for TB preventive treatment in line with WHO recommendations, increasing investments and building synergies with contact tracing efforts for the COVID-19 response. Promote and expand access to testing for TB infection and TB preventive treatment with new medicines and shorter regimens, with social support. Continue to expand the coverage of TB preventive treatment for people living with HIV alongside antiretroviral treatment.

Given that promotion and protection of the human rights of people affected by TB is a legal, ethical and moral imperative, and that people affected by TB and TB-associated impairments and disabilities continue to be subjected to human rights violations which together with stigma and discrimination impede access to care and add to the suffering caused by the disease: Review and update laws, policies and programmes to combat inequalities and eliminate stigma and discriminatory practices in the TB response, working together with civil society and affected communities and with particular attention to vulnerable populations. Ensure that national TB strategies, plans, policies and other documentation avoid stigmatizing language.

Given that engagement of civil society, communities and people affected by TB is essential to the TB response, and that while this has grown since the UN high-level meeting on TB accelerated efforts are needed to ensure more extensive engagement: Actively invest in building the capacity of civil society, representatives of affected communities including TB survivors, and people affected by TB-associated impairment and disability to ensure their meaningful engagement in all aspects of the TB response, including in policy making forums, planning, care delivery, monitoring and review.
Given that global funding for TB research needs to more than double to reach the annual target of US$ 2 billion, that chronic underfunding of TB research means there are still no point of care tests, treatments remain long, the only licensed vaccine is over 100 years old and provides limited protection, and that ending TB depends on the development and rapid uptake of new tools and innovation: Increase investment in TB research and innovation to at least US$ 2 billion per year from national governments, bilateral and multilateral financing sources as well as development and private sector institutions. Develop and implement actionable, fully-funded and well-resourced national strategies for TB research and innovation, building on the WHO Global Strategy for TB Research and Innovation, in collaboration with research networks, relevant non-state actors, international agencies and TB community advisory boards. As a matter of urgency, support the implementation of Phase II and Phase III trials for the most promising TB vaccine and drug candidates. Ensure that TB diagnostics and drugs are prioritized for fast-track review by national regulatory authorities and considered for inclusion in essential lists. Rapidly adopt and implement innovations including digital technologies related to the different aspects of TB prevention and care.

Given the enormous health, social and economic impact of the COVID-19 pandemic, which in 2020 alone may cause hundreds of thousands of excess TB deaths due to disruptions of essential TB services and access to care, that national TB programmes are already heavily engaged in the COVID-19 response, and that there are obvious similarities in the responses needed for both TB and COVID-19: Ensure that TB prevention, diagnosis and treatment are maintained as essential health services in the context of health emergencies, with infection prevention and control measures in place for health facilities and affected households. Monitor and review the impact of the COVID-19 pandemic on the TB response including with the engagement of civil society and affected communities, to inform timely action. Build back stronger by learning lessons from the COVID-19 pandemic, including by enhancing the resilience of TB programmes during emergencies, implementing catch-up recovery plans to reach targets, and harnessing innovations such as digital technologies.
Given that WHO as the UN specialized agency for health provides global leadership and coordination for the TB response, in collaboration with stakeholders such as the Global Fund, Stop TB Partnership, Unitaid, civil society and other entities, and that as requested in the political declaration has finalized the Multisectoral Accountability Framework for TB and is supporting its adaptation and use, WHO is requested to: Continue to provide leadership and coordination to accelerate progress, including through political dialogue and multisectoral engagement; normative guidance and technical support to Member States; monitoring, reporting and review; and shaping of the TB research and innovation agenda. Continue to support Member States to adapt and use the Multisectoral Accountability Framework for TB in collaboration with partners, civil society and affected communities, and lead periodic global reviews of the TB response. Support the Office of the UN Secretary General to prepare a comprehensive review by Heads of State and Government at a UN high level meeting on TB in 2023, informed by WHO’s Global TB Report, global, regional and national high-level reviews and preceded by an interactive civil society hearing.

Request WHO to continue to provide global leadership for the TB response, working in close collaboration with Member States and other stakeholders, including to prepare for a High-Level Meeting on TB in 2023.
References


