Global strategy for tuberculosis research and innovation

Report by the Director-General

BACKGROUND

1. Tuberculosis, a preventable and curable communicable disease, is one of the leading causes of death from an infectious agent worldwide. It is also the foremost cause of death of people living with HIV and among the top contributors to disease and death from drug-resistant infections. The Seventy-third World Health Assembly in resolution WHA73.3 (2020) adopted the global strategy for tuberculosis research and innovation. It also requested the Director-General to submit a report on progress in respect of the End TB Strategy, including progress on the implementation of the global strategy for tuberculosis research and innovation, for consideration by the Seventy-fifth World Health Assembly in 2022 through the Executive Board at its 150th session, to inform preparations for the comprehensive review by Heads of State and Governments at a United Nations high-level meeting on tuberculosis in 2023, as requested in United Nations General Assembly resolution 73/3 (2018).

2. The coronavirus disease (COVID-19) pandemic has significantly affected the tuberculosis response, with serious implications on progress towards ending tuberculosis. In this regard, the report summarizes activities based on the commitments made by Member States in resolution WHA73.3, the 2018 high level meeting of the General Assembly on the fight against tuberculosis, the Moscow Declaration to End TB (2017), resolution WHA67.1 (2014) and in related regional committee resolutions and documents, taking into account shifts created by the COVID-19 pandemic. It includes information on progress by Member States and the work of the Secretariat across all three levels of the Organization, including on aspects of global monitoring, reporting, review, normative guidance, technical and strategic support, global coordination and leadership. It builds on the 2019 report of the Director-General to the Executive Board, the 2020 report of the United Nations Secretary-General to the General Assembly, and the Global tuberculosis report 2021.

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1 See document A67/11 and resolution WHA67.1 (2014).
2 See document EB144/21.
3 See document A/75/236.
PROGRESS IN THE IMPLEMENTATION OF THE END TB STRATEGY

Commitments, milestones and targets

3. A summary of the targets, milestones, principles, pillars and associated components of the End TB Strategy is available online. The table below provides additional global targets adopted by the United Nations General Assembly in the high-level meeting on the fight against tuberculosis in 2018. Unless otherwise stated, all statistics presented here are drawn from the Global tuberculosis report 2021.

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of people with tuberculosis diagnosed and treated</td>
<td>40 million people, including 3.5 million children, and 1.5 million people with drug-resistant tuberculosis, including 115,000 children, over the period 2018–2022</td>
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<tr>
<td>Number of people reached with treatment to prevent tuberculosis</td>
<td>At least 30 million people, including 4 million children under 5 years of age, 20 million other household contacts of people affected by tuberculosis, and 6 million people living with HIV, over the period 2018–2022</td>
</tr>
<tr>
<td>Global mobilization of sufficient and sustainable financing for universal access to quality prevention, diagnosis, treatment and care of tuberculosis</td>
<td>At least US$ 13 billion annually by 2022</td>
</tr>
<tr>
<td>Mobilization globally of sufficient and sustainable financing for tuberculosis research</td>
<td>US$ 2 billion annually, over the period 2018–2022</td>
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IMPACT OF COVID-19

4. The response to the COVID-19 pandemic has adversely affected essential tuberculosis services in many countries. This is estimated to have caused a substantial fall in the global number of tuberculosis case notifications between 2019 and 2020 (18%, from 7.1 million to 5.8 million), with the largest reductions in the South-East Asia and the Western Pacific regions. Globally, deaths from tuberculosis increased from 1.4 million to 1.5 million in 2020. The COVID-19 pandemic has exacerbated the socioeconomic determinants of tuberculosis such as poverty and under-nutrition, which will add to the burden of tuberculosis disease and death. Other impacts include a downturn in the number of people initiated on tuberculosis preventive treatment (from 3.6 million to 2.8 million), a reduction in spending on tuberculosis services (from US$ 5.8 billion to US$ 5.3 billion), a 15% decrease in the number of people provided with treatment for drug-resistant tuberculosis and a reduction in coverage of the bacille Calmette-Guérin vaccine (5% or more in 31 countries).

5. WHO has been monitoring the impact of the COVID-19 response on tuberculosis notification on a monthly basis in over 100 countries, providing guidance and sharing lessons from case studies of programmatic innovations to address emerging challenges in tuberculosis prevention and care. The Secretariat across all three levels of the Organization is working closely with countries, the Global Fund to Fight AIDS, Tuberculosis and Malaria, the STOP TB partnership and other partners to mitigate the pandemic’s impact on tuberculosis services.

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PROGRESS TOWARDS GLOBAL TUBERCULOSIS TARGETS

6. **Tuberculosis incidence and mortality.** In 2020, 9.9 million people were estimated to have fallen ill with tuberculosis. The cumulative reduction in tuberculosis incidence per 100 000 population from 2015 to 2020 was 11%, compared to the milestone of 20% reduction set by the End TB Strategy for 2020. Globally, 86 countries reached the 2020 End TB Strategy milestone in tuberculosis incidence reduction. The WHO European Region exceeded the 2020 milestone, with a reduction of 25%, while the African Region came close, with a reduction of 19%.

7. Between 2019 and 2020, the global number of tuberculosis deaths (including deaths among people living with HIV) increased from 1.4 million to 1.5 million, reversing progress to the level of 2017. This is the first annual increase in the number of people dying from tuberculosis since 2005 and is attributed to the adverse impact of the COVID-19 pandemic. Overall, instead of the targeted milestone of 35% reduction in the number of tuberculosis deaths between 2015 and 2020, there was a reduction of only 9.2%. However, 33 countries have managed to achieve the milestone in reduction of the number of tuberculosis deaths. WHO has updated its global list of countries with a high burden of tuberculosis.1 Cambodia, the Russian Federation and Zimbabwe have transitioned out of the list of high burden countries, while Gabon, Mongolia and Uganda have joined.

8. **Costs faced by tuberculosis patients.** According to national surveys, on average 47% of tuberculosis patients and their households faced costs, including direct medical expenditures, direct non-medical payments such as transportation and lodging, and indirect costs such as lost income, that exceeded 20% of annual household income. This figure is far from the target of the End TB Strategy, namely that no tuberculosis-affected households should face costs of this magnitude. The proportion is higher for patients with drug-resistant tuberculosis and their households (87% pooled average). Survey results show that no country has yet met the target.

9. **People registered and treated for tuberculosis.** The most obvious impact on tuberculosis of disruptions caused by the COVID-19 pandemic is a large global drop (18%) in the number of people newly diagnosed with tuberculosis and reported. This brings the gap between the number of people who fell ill with tuberculosis and the number of people newly diagnosed and reported to substantially increase to 4.1 million. Two WHO regions accounted for most (84%) of the global reduction in notifications: South-East Asia and the Western Pacific. The cumulative number of people treated between 2018 and 2020 was 19.8 million, equivalent to 50% of the 5-year (2018–2022) target of 40 million. This included 1.4 million children, 41% of the 5-year target of 3.5 million.

10. Regarding drug-resistant tuberculosis, there was a drop in the number of people notified and enrolled on treatment. A total of 157 903 people with drug-resistant tuberculosis were notified in 2020, a 22% fall from 2019. A total of 150 359 people were enrolled on treatment in 2020, down 15% from 2019. Overall, one in three people who develop drug resistance were enrolled on treatment, making achievement of the global targets increasingly out of reach. The cumulative number of people with drug-resistant tuberculosis reported as enrolled on treatment from 2018 to 2020 was 482 683, only 32% of the 5-year target (2018–2022) of 1.5 million. Considering children specifically, the cumulative number was 12 219, only 11% of the 5-year target of 115 000. Actions to mitigate and reverse these impacts are urgently needed to end this public health crisis.

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11. **People treated to prevent tuberculosis disease.** In 2020 the number of people started on tuberculosis preventive treatment declined globally by 21%, from 3.6 million to 2.8 million. The cumulative number of children under 5 years started on tuberculosis preventive treatment was 1.2 million (29% of the 4 million target), while for other household contacts was 0.32 million (1.6% of the 20 million target). In contrast, the 6 million target for people living with HIV was exceeded by 1.2 million. This indicates that far more needs to be done to identify child and adult household contacts, and to initiate tuberculosis preventive treatment for those eligible. A call to action by the Director-General urged countries and partners to accelerate the scale-up of tuberculosis preventive treatment to reach the global target set at the high-level meeting of the General Assembly on the fight against tuberculosis.

12. **Financing for universal access to care and prevention, and for tuberculosis research and development.** Funding for tuberculosis services continues to fall far short of the globally estimated need and the United Nations global target. Based on data reported, US$ 5.3 billion was available in 2020, an 8.7% fall from 2019 and well below the target of US$ 13 billion annually by 2022. Of the total funding available in 2020, 81% was from domestic sources, with the BRICS countries (Brazil, China, India, the Russian Federation and South Africa) accounting for 65% of total domestic funding. The largest bilateral donor is the Government of the United States of America. The biggest international donor is the Global Fund to Fight AIDS, Tuberculosis and Malaria, although the share of resources allocated for tuberculosis is currently fixed at 18%. This should be increased to address critical gaps in financing, particularly for low-income countries. Annual funding for low- and middle-income countries needs to more than double to reach the United Nations global target of US$ 13 billion per year.

13. The Treatment Action Group reported tuberculosis research and development investment of US$ 901 million in 2019, far below the target of at least US$ 2 billion per year. Annual funding for tuberculosis research needs to more than double to reach the global target.

### Progress in implementing the principles, pillars and components of the End TB Strategy

14. **Adaptation of the strategy and targets at country level, with global collaboration.** WHO encourages and supports countries with a high tuberculosis burden to prioritize tuberculosis in recovery or maintenance plans of essential health services during COVID-19, and is leading efforts to enhance collaboration across stakeholders towards ending the epidemic. The Director-General’s FIND.TREAT.ALL#ENDTB flagship initiative, implemented jointly with the Stop TB Partnership and the Global Fund to Fight AIDS, Tuberculosis and Malaria, is continuing to help scale up access to tuberculosis services to reach the 2022 targets, in the context of WHO’s Thirteenth General Programme of Work, 2019–2023. Over 10 high-level missions were undertaken by WHO to promote accountability and the investment required to translate political commitments into action. The Secretariat supported the development of the United Nations Secretary-General’s report on 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. The report provides 10 priority

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3. See document A/75/236.
recommendations to put the world on track to ending tuberculosis by 2030 (see the annex to the present report).

15. The Secretariat is providing support to countries to reduce tuberculosis deaths urgently and drive multisectoral action to end tuberculosis through the WHO multisectoral accountability framework. Presidential or Head of State initiatives to end tuberculosis in India, Indonesia, Pakistan, Philippines, the Russian Federation and Viet Nam are demonstrating high-level leadership on multisectoral accountability through formalized mechanisms. National campaigns to drive progress such as the “Race to End TB” are continuing. A road map to scale up public–private health provider engagement developed by WHO and the Stop TB Partnership in 2018 is being implemented in at least 20 countries with a high tuberculosis burden. Support is also being provided to countries with a low tuberculosis burden to work towards elimination. The WHO Strategic and Technical Advisory Group for tuberculosis is providing advice and reviewing the actions required to accelerate progress.

16. Engagement of civil society and communities affected is vital for an effective tuberculosis response. Political commitment and investment are needed to strengthen the engagement of affected communities and civil society. The WHO Civil Society Task Force on Tuberculosis is meeting regularly and engaging with the Director-General, governments, guideline development groups and other bodies at global and regional levels to mainstream civil society and affected community perspectives of the tuberculosis response at all levels. The Task Force in a joint statement with the Director-General called for urgent actions to stop preventable deaths and suffering due to tuberculosis and to recover gains lost during the COVID-19 pandemic.

17. Pillar 1: Integrated patient-centred care and prevention. To optimize tuberculosis care and improve treatment outcomes, the adoption and implementation of latest tuberculosis WHO guidance is important. New consolidated guidelines and operational handbooks have been issued for the screening and diagnosis of tuberculosis and for the treatment of drug-susceptible tuberculosis, drug-resistant tuberculosis and tuberculosis infection. A tuberculosis digital knowledge sharing platform (including applications for smartphones and tablet computers) and an online searchable repository of recommendations from tuberculosis guidelines (WHO eTB Guidelines) were developed to improve access and use of the latest policy guidance.

18. Strategies to improve diagnosis and initiation of care for people with tuberculosis are imperative to reach the End TB targets. To date, the use of WHO-recommended rapid molecular tests remains far too limited. Rapid tests were used as the initial diagnostic test for 1.9 million (33%) of the 5.8 million people newly diagnosed with tuberculosis in 2020, compared to 2 million (28%) of a total of 7.1 million in 2019. The global coverage of HIV testing among people diagnosed with tuberculosis remained high in 2020, at 73% (up from 70% in 2019). However, the absolute number fell from 4.8 million in 2019

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to 4.2 million in 2020, a reduction of 15%. The coverage of antiretroviral therapy among people diagnosed with tuberculosis and known to be HIV-positive was 88% in 2020, the same level as in 2019.

19. The treatment success rate for drug-resistant tuberculosis (59%) remains significantly lower than for people treated for tuberculosis with first-line regimens (86%). Scaling up the implementation of the most recent guidance on tuberculosis treatment can improve these outcomes. Ninety countries are using all-oral longer regimens for the treatment of drug-resistant tuberculosis (up from 86 in 2019), and 65 countries are using shorter regimens. WHO, in collaboration with Global Fund, provided technical support for the adoption of all-oral regimens for the treatment of drug-resistant tuberculosis in 88 countries through the Green Light Committee mechanism. WHO together with the Global Drug Facility of the Stop TB Partnership and other partners is facilitating access to quality tuberculosis medicines.

20. **Pillar 2: Bold policies and systems.** Experiences from countries during the pandemic demonstrate that robust health systems are a prerequisite for an effective response to existing and emerging health threats. Most of the 30 countries with the highest tuberculosis burden\(^1\) have below-average index levels for health service coverage, a situation which is likely to have been exacerbated by adverse impacts of the pandemic. The Secretariat has developed operational guidance for countries on the maintenance of essential health services, such as for tuberculosis, during the pandemic, on community-based health care and on how to prepare for the recovery phase. Digital surveillance mechanisms are being expanded by countries to strengthen tuberculosis response. As of August 2021, 130 countries and territories report having in place a digital, case-based surveillance system that covers all people diagnosed and reported with tuberculosis. WHO together with partners is supporting the implementation by countries of digital packages for the collection, analysis, visualization and use of data from routine health facility information systems.\(^2\) In 2020, 81 countries reported data on community contributions to referrals of people with tuberculosis symptoms to health facilities. Improvement in vital registration systems is still slow. Private sector engagement and novel partnerships are critical priorities for further increasing case notifications.

21. The number of people newly diagnosed with tuberculosis attributable to top risk factors in 2020 include 1.9 million to undernourishment, 0.73 million to smoking, 0.74 million to hazardous and harmful alcohol use, 0.74 million to HIV infection and 0.37 million to diabetes. Multisectoral actions are important in order to address the determinants and consequences of tuberculosis. WHO is working with countries, other United Nations entities and partners to foster multisectoral collaboration and social support based on the needs identified from tuberculosis patient cost surveys.

22. **Pillar 3: Intensified research and innovation:** Reaching the End TB targets will require the development and scale-up of technological advances by 2025. In 2020, there were at least 22 medicines, 14 vaccines and several diagnostics in clinical development. By mid-2021, the number of medicines had increased to 25, while the vaccine and diagnostics pipeline remained more or less similar to the situation in 2020. Strong government leadership is required to mobilize domestic resources, foster public–private partnerships and incentivize the engagement of pharmaceutical companies, biotechnology firms and other health product developers to expand the pipeline of new tuberculosis tools.

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\(^1\) The 30 countries are: Angola, Bangladesh, Brazil, Central African Republic, China, Congo, Democratic People’s Republic of Korea, Democratic Republic of the Congo, Ethiopia, Gabon, India, Indonesia, Kenya, Lesotho, Liberia, Mozambique, Mongolia, Myanmar, Namibia, Nigeria, Pakistan, Papua New Guinea, Philippines, Sierra Leone, South Africa, Thailand, Viet Nam, Uganda, United Republic of Tanzania and Zambia.

IMPLEMENTATION OF THE GLOBAL STRATEGY FOR TUBERCULOSIS RESEARCH AND INNOVATION

23. The Global strategy for tuberculosis research and innovation aims to accelerate technological breakthroughs and rapid uptake of innovations. To facilitate the adaptation of the strategy, WHO developed a situational assessment checklist to help countries contextualize the implementation of the strategy through changes in policies, programmes and interventions, and is providing technical support with its implementation initially focusing on high tuberculosis burden countries. WHO, in collaboration with partners including bilateral agencies, foundations and the UNICEF/UNDP/WHO/World Bank Special Programme for Research and Training in Tropical Diseases, continues to support implementation research projects and capacity-building. WHO is providing support to the secretariat of the tuberculosis research network of the BRICS countries.

24. WHO through an independent expert committee updated its lists of essential medicines, including for children. Major updates for antituberculosis medicines include the addition of two child-friendly formulations of medicines for the treatment of multi-drug resistant tuberculosis in children and new formulations, including a fixed-dose combination, for tuberculosis preventive treatment and drug-sensitive tuberculosis. Unitaid, the Stop TB Partnership and the Global Fund to Fight AIDS, Tuberculosis and Malaria are facilitating equitable access to tuberculosis-related innovations, including medicines.

25. Funding for tuberculosis research and development for 2019 (US$ 901 million) was less than half of the US$ 2 billion per year target set in the political declaration of the high-level meeting of the General Assembly on the fight against tuberculosis. Approximately one third of tuberculosis research funding was for drug research, followed by 19% for basic science, 16% for operational research, 13% for vaccines, 10% for diagnostics and 8% for infrastructure/unspecified research. The amount needs to more than double to reach the global target.

26. Rapid sharing of data greatly accelerates research, discovery and policy-making, as demonstrated by the response to the COVID-19 pandemic. To address unmet needs in translational research, several high tuberculosis burden countries, including members of the BRICS tuberculosis research network are collecting and analysing data and biospecimens from tuberculosis patients using common protocols coordinated through the Regional Prospective Observational Research for Tuberculosis (RePORT) network. To inform policy updates, WHO is regularly conducting calls for data sharing and managing a platform with individual patient data for drug-resistant tuberculosis treatment. New, effective and safe tuberculosis vaccines are urgently needed to accelerate reduction in tuberculosis incidence and mortality. WHO is implementing a health and economic impact assessment to develop the evidence on social, economic and population-health impacts necessary to guide further investments in late-stage research, introduction and implementation of new tuberculosis vaccines. Support will continue to be

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provided to countries for the adaptation and implementation of the global strategy for tuberculosis research and innovation.

CONCLUSION

27. Progress towards tuberculosis milestones and targets has been hit hard by the COVID-19 pandemic. In 2020, the number of people dying from tuberculosis increased, previous declines in the annual number of people falling ill with tuberculosis slowed, far fewer people were diagnosed and treated for tuberculosis or provided with tuberculosis preventive treatment compared with 2019 and spending on essential tuberculosis services fell. This poses a risk to the achievement of the targets set in the political declaration of treating 40 million people diagnosed with tuberculosis and providing tuberculosis preventive treatment to 30 million people by 2022. To reverse the impact of the pandemic, avert preventable deaths and put the world on track to end tuberculosis, essential tuberculosis services must be restored as a matter of urgency, 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 tuberculosis response, working in close collaboration with all stakeholders, including to prepare for a high-level meeting on tuberculosis in 2023.

ACTION BY THE EXECUTIVE BOARD

28. The Board is invited to note the report, and in its discussions, it is further invited to provide guidance on how WHO can best:

   (a) support high-level leadership by countries to drive the investment and multisectoral action required to ensure recovery of essential tuberculosis services, avert preventable tuberculosis deaths and achieve faster progress towards global tuberculosis targets;

   (b) accelerate the implementation of the global strategy for tuberculosis research and innovation together with the investments necessary to facilitate the development and rapid uptake of new tools and strategies;

   (c) support and inform preparations for the upcoming comprehensive review by Heads of State and Government at a United Nations General Assembly high-level meeting on tuberculosis in 2023.
ANNEX


The report of the Secretary-General urged Member States to implement the following 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 tuberculosis.

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

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

3. Advance universal health coverage to ensure all people with tuberculosis have access to affordable quality care, and resolve underreporting challenges.

4. Address the drug-resistant tuberculosis crisis to close persistent gaps in care.

5. Dramatically scale up provision of preventive treatment for tuberculosis.

6. Promote human rights and combat stigma and discrimination.

7. Ensure meaningful engagement of civil society, communities and people affected by tuberculosis.

8. Substantially increase investments in tuberculosis research to drive technological breakthroughs and the rapid uptake of innovations.

9. Ensure that tuberculosis prevention and care are safeguarded in the context of COVID-19 and other emerging threats.

10. Request the World Health Organization to continue to provide global leadership for the tuberculosis response, working in close collaboration with Member States and other stakeholders, including to prepare for a high-level meeting on tuberculosis in 2023 that aligns with the high-level meeting of the General Assembly on universal health coverage also to be held in 2023.

¹ See document A/75/236.