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## **Ending tuberculosis**

### **Draft global strategy for tuberculosis research and innovation**

#### **Report by the Director-General**

1. In May 2018 the Seventy-first World Health Assembly adopted resolution WHA71.3 on preparation for a high-level meeting of the General Assembly on ending tuberculosis. In the resolution, the Director-General of WHO was requested to develop a global strategy for tuberculosis research and innovation.
2. The drafting of the strategy was guided by the target of ending the tuberculosis epidemic by 2030, as defined in the Sustainable Development Goals and the WHO End TB Strategy.<sup>1</sup> To inform the development of the draft strategy, consultations were held with the WHO Strategic and Technical Advisory Group for Tuberculosis, the WHO Global TB Research Task Force, national tuberculosis programme managers and other officials from within and beyond ministries of health, including ministries of science and technology, and representatives of civil society and affected communities, research funding institutions, and other tuberculosis research and innovation stakeholders. A draft document was made available online for public review in the second quarter of 2019, and based on feedback received, a revised draft document was made available for consideration by WHO regional committees. Briefings for several Member States were also held in the third quarter of 2019 in Geneva.
3. A set of proposed activities, and suggestions for monitoring and evaluating progress have been incorporated into the strategy in order to guide implementation. However, additional planning at the country level will be required to ensure appropriate implementation.
4. This document is a summary of the draft global strategy. The full strategy can be accessed at [https://www.who.int/tb/research/GlobTBResStrategy\\_2019.pdf](https://www.who.int/tb/research/GlobTBResStrategy_2019.pdf).<sup>2</sup>

#### **BACKGROUND AND CONTEXT**

5. Tuberculosis is the leading cause of death from a single infectious agent globally, and is one of the leading causes of death from antimicrobial resistance. The Sustainable Development Goals include a target for tuberculosis that builds on historic gains made under the Millennium Development Goals,

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<sup>1</sup> End TB Strategy: global strategy and targets for tuberculosis prevention, care and control after 2015. Geneva: World Health Organization; 2014 ([https://www.who.int/tb/strategy/End\\_TB\\_Strategy.pdf?ua=1](https://www.who.int/tb/strategy/End_TB_Strategy.pdf?ua=1), accessed 11 October 2019).

<sup>2</sup> In line with resolution WHA69.19 (2016) on the global strategy on human resources for health: workforce 2030, a health workforce impact assessment was carried out for the draft global strategy for tuberculosis research and innovation (see [http://www.who.int/hrh/activities/HealthWorkforceImpactAssessment\\_TB\\_Oct2019.pdf](http://www.who.int/hrh/activities/HealthWorkforceImpactAssessment_TB_Oct2019.pdf), accessed 7 November 2019).

to “end the epidemic” by 2030. More specific targets for 2030 were set in WHO’s End TB Strategy; they include ensuring that no family is burdened with catastrophic expenses due to tuberculosis, and achieving a 90% reduction in tuberculosis deaths and an 80% reduction in tuberculosis incidence compared with 2015 levels, with targets for further reductions in deaths and incidence (95% and 90%, respectively) by 2035. However, there is still an enormous gap between current reality and the vision of the Sustainable Development Goals.

6. Robust efforts are needed to sustain and improve on the gains made to date, and to address persistent challenges that have led to uneven progress in the fight against tuberculosis, including from the complex challenges created by the rise of drug-resistant forms of tuberculosis. The End TB Strategy stipulates that major technological breakthroughs are needed by 2025 in order to increase dramatically the rate at which tuberculosis incidence falls compared with historic levels. Delivering on these targets requires a multisectoral approach to developing and equitably diffusing the most appropriate medical and programmatic innovations as a top priority. However, there are multiple challenges and gaps to be addressed in research, innovation and access to tuberculosis vaccines, medicines, technologies and services.

7. In both the 2018 political declaration of the high-level meeting of the General Assembly on the fight against tuberculosis<sup>1</sup> and the 2017 Moscow declaration to End TB,<sup>2</sup> which followed the WHO global ministerial conference on ending TB, Member States renewed their commitment to strengthen national and global efforts in the fight against tuberculosis. The draft global strategy aims to provide countries with a framework to facilitate the implementation of the commitments on research and innovation that were articulated in the declarations.

8. Implementation of those commitments should align with the demands of patients and health care systems, to ensure that innovations address both health and non-health determinants of tuberculosis, are affordable and accessible, and can be made available sustainably, given that most people with tuberculosis disease are in low- and middle-income countries, or are often among vulnerable and hard-to-reach risk groups in both low and high tuberculosis incidence countries. In promoting health system research, there is a need for mechanisms that steer innovation towards sustainable, ethically acceptable and socially desirable interventions that are communicated effectively in the affected community’s local language.

9. Great efforts have been made to replenish the research and development pipeline for tuberculosis in the past decade. However, if promising tools are to progress through the pipeline and generate public health benefits, increased and sustained funding will be needed to optimize their dissemination, particularly during the later stages of product development (including product registration, market authorization and manufacturing), and for operational/implementation, health system and social science research.

10. Most national tuberculosis programmes have weak links to public research institutes and universities, and few incentives and resources for innovation. Coupled with weak research

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<sup>1</sup> Political Declaration of the High-Level Meeting of the General Assembly on the fight against tuberculosis [73/3]. New York: United Nations General Assembly; 2018 ([https://www.un.org/en/ga/search/view\\_doc.asp?symbol=A/RES/73/3](https://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/73/3), accessed 11 October 2019).

<sup>2</sup> Moscow Declaration to End TB. Geneva: World Health Organization; 2017 ([https://www.who.int/tb/features\\_archive/Online\\_Consultation\\_MinisterialConferenceDeclaration/en/](https://www.who.int/tb/features_archive/Online_Consultation_MinisterialConferenceDeclaration/en/), accessed 11 October 2019).

infrastructure, low numbers of academic researchers and a heavy reliance on foreign funding for research in many high tuberculosis burden countries, this has slowed the pace of local innovations.

11. The Stop TB Partnership's *Global Plan to End TB, 2016–2020: the paradigm shift* estimates that the world needs to spend about US\$ 2 billion on research and development in tuberculosis annually to deliver the necessary innovations required to end tuberculosis. However, currently, only one third of the required financial investment needs are being met. Moreover, funding is highly concentrated: 30 institutions from a handful of countries account for more than 90% of tuberculosis research and development expenditures in any given year.<sup>1</sup>

12. Tuberculosis research also suffers from a complex regulatory environment in some countries. Policies that encourage research and innovation while also ensuring safety and objectivity are critical to help transfer new ideas to the market, and to attract and sustain private sector engagement. Examples of such policies are those that include an expedited ethics review process and have predictable and expedited product evaluation and registration processes that do not compromise national, regional and global respect for ethical boundaries or intellectual property rights.

13. About a quarter of a million people die annually from drug-resistant tuberculosis. The spread of drug resistance is a major public health concern that threatens to make tuberculosis an untreatable and highly fatal disease, particularly in low-resource settings. Without an intervention, tuberculosis is projected to be one of the three biggest drivers of the economic toll of antimicrobial resistance, alongside malaria and *Escherichia coli*, with an estimated 2.5–3.0% loss to global gross domestic product that will reach US\$ 100 trillion by 2050.<sup>2</sup> Already, a disproportionately high share of national tuberculosis budgets is allocated to the treatment of drug-resistant tuberculosis, owing to the complexity and high cost of managing this form of the disease. Improvements in the treatment of drug-resistant tuberculosis will therefore increase the budget available for scaling up services in other aspects of tuberculosis prevention, diagnosis, treatment and care.

14. The field of tuberculosis prevention and care is challenged by a lack of equitable access to medicines and technologies, and low availability or use of services by the populations that need them most.

15. Although there is a considerable amount of useful data available on tuberculosis detection, pharmacovigilance, clinical testing and surveillance, a major hurdle is the timely sharing of high-quality data with policy-makers and researchers in order to guide policy, clinical practice and future research. Considering the public health crisis of drug-resistant tuberculosis, it is particularly important for countries to adopt better practices for sharing data related to both surveillance and pharmacovigilance.

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<sup>1</sup> Frick M. Tuberculosis research funding trends 2005–2017 New York: Treatment Action Group; 2018 (<http://www.treatmentactiongroup.org/content/tbrd2018?eType=EmailBlastContent&eId=7dac4161-dc99-43a2-9447-4d18aeb4c8ac#overlay-context=content/tbrd2018>, accessed 11 October 2019).

<sup>2</sup> Tackling drug-resistant infections globally: final report and recommendations. London: The Review on Antimicrobial Resistance; 2016 ([https://amr-review.org/sites/default/files/160518\\_Final%20paper\\_with%20cover.pdf](https://amr-review.org/sites/default/files/160518_Final%20paper_with%20cover.pdf), accessed 11 October 2019).

## OBJECTIVES AND RECOMMENDATIONS

16. The global strategy for tuberculosis research and innovation will support efforts by governments and other partners to accelerate tuberculosis research and innovation, and to improve equitable access to the benefits of research, by setting clear objectives and recommendations, as highlighted below.

(a) **Create an enabling environment for high-quality tuberculosis research and innovation** to increase the capacity for conducting and using research outcomes equitably in a sustained and effective manner. This can be achieved by streamlining and harmonizing regulatory processes to enable efficient review of research protocols and products, and to reduce trade and distribution mark-ups on the prices of essential tuberculosis medicines and technologies. Creating an enabling environment also entails strengthening public–private partnerships and integrating civil society’s expectations, needs, interests and values into the research and development process.

Such efforts should be complemented by the development and implementation of country-specific tuberculosis research agendas that are aligned with national health research strategic plans, in order to expand and accelerate tuberculosis research at the country level through capacity-building and collaboration among other actors in the innovation system. In addition, increasing the number and profile of local researchers engaged in tuberculosis research, and providing the necessary incentives to retain researchers in employment, will help to deliver the research training, infrastructure and incentives required to stimulate innovation and increase the capacity to make use of innovations.

(b) **Increase financial investments in tuberculosis research and innovation** by increasing overall contributions for tuberculosis research funding. One way in which this can be achieved is by setting a target contribution for the conduct of the social, health system and operational/implementation research that is vital to support effective scale-up of innovative strategies and tools. Another approach is to develop innovative and collaborative financing mechanisms to facilitate the timely development and diffusion of appropriate and affordable biomedical tools and technologies.

(c) **Promote and improve approaches to data sharing** to advance scientific discovery and dissemination of findings, reduce duplication of effort and facilitate the translation of evidence to national and global policies on tuberculosis prevention, diagnosis, treatment and care, including by making use of new and existing scientific academic forums. This can be accomplished by developing or strengthening a policy of open access to and open data for scientific research (both nationally and globally) that receives public funds; establishing or strengthening national health information and vital registration systems for the collection of high-quality data that allow for reliable tracking of the tuberculosis epidemic (in terms of absolute numbers and trends in incidence and deaths), so that subnational, national, regional and global trends can be detected and monitored and can inform decision-making; and fostering voluntary technology-transfer policies that enable the development and diffusion of knowledge, and the wider transfer of evidence to policy and practice. Publicly searchable patent databases also promote the diffusion of knowledge by facilitating access to the information disclosed in a patent.

(d) **Promote equitable access to the benefits of research and innovation** by strengthening global access initiatives for tuberculosis prevention and care. This can be achieved, for example, by supporting the replenishment of global financing mechanisms such as Unitaid and the Global Fund to Fight AIDS, Tuberculosis and Malaria, and by providing appropriate governance structures that foster research and innovation as a shared responsibility that is needs driven,

evidence based and guided by the core principles of affordability, effectiveness, efficiency and equity. Strengthening access initiatives entails ensuring the availability of the most recent guidelines on the prevention, diagnosis and treatment of tuberculosis at all levels of the health system; including tuberculosis technologies and medicines in national essential medicine and technology lists, while retaining effective supply-chain management to facilitate the procurement and use of high-quality medicines and technologies; developing policies on trade, health and intellectual property through multisectoral collaborative frameworks, to help address access and innovation simultaneously; and developing regulatory frameworks and fostering partnerships across sectors to reduce trade and distribution mark-ups on the prices of essential tuberculosis medicines and technologies, and to support policies that promote transparency in the public disclosure of clinical trial data.

## **IMPLEMENTATION AND MONITORING PROGRESS**

17. Governments have a key role in facilitating the strengthening of policies related to the four main objectives stated in this strategy. However, national approaches will vary as a result of differences in economic, institutional, regulatory and human resource capacity and in aspects of policy such as the role of public versus private sectors in research and innovation. Translating this strategy into effective and appropriate actions at both local and national levels may require the development of a national strategy or road map for tuberculosis research that is framed around country needs and context.

18. Systematic monitoring and evaluation of efforts by Member States, appropriate to each country's context, is needed to ensure that the necessary policy changes are being made and implemented, and to track whether the policies implemented are having an impact that is linked to achieving the goals and targets set in national tuberculosis strategic plans and the End TB Strategy. The multisectoral accountability framework to accelerate progress to end tuberculosis presents an opportunity to monitor such progress;<sup>1</sup> its implementation would allow policy-makers to learn from ongoing efforts, and from the exchange of experiences and good practices across countries.

19. In the spirit of fast-tracking efforts to end tuberculosis, a prerequisite for success is that all stakeholders make concerted efforts and collaborate. Hence, this document also makes the case for a unified and aligned response in which key relevant national and international partners and affected communities support Member States by committing to the investments or partnerships (or both) necessary for accelerating innovation.

## **ACTION BY THE EXECUTIVE BOARD**

20. The Board is invited to consider the following draft decision.

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<sup>1</sup> Multisectoral accountability framework to accelerate progress to end tuberculosis by 2030. Geneva: World Health Organization; 2019 (<https://www.who.int/tb/publications/MultisectoralAccountability/en/>, accessed 11 October 2019).

The Executive Board, having considered the report on the draft global strategy for tuberculosis research and innovation,<sup>1</sup> decided to recommend to the Seventy-third World Health Assembly the adoption of the following decision:

The Seventy-third World Health Assembly, having considered the draft global strategy for tuberculosis research and innovation, decided:

- (1) to endorse the global strategy on tuberculosis research and innovation; and
- (2) to request the Director-General to submit a report on progress made in the implementation of the global strategy to the Health Assembly in 2023.

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<sup>1</sup> Document EB146/11.