A global strategy for tuberculosis research and innovation

To the Editor:

We read with interest the editorial by Saunders and Evans [1] summarising the high risk the coronavirus 2019 (COVID-19) pandemic poses with regard to reversing the gains made to date on ending tuberculosis (TB), and the urgent need for innovative solutions to address the clinical, social and economic determinants of the disease. TB is the leading cause of death from a single infectious agent globally, and the impact of the COVID-19 pandemic risks making TB even more catastrophic. Effective diagnosis and treatment have saved an estimated 58 million lives between 2000 and 2018 [2], but despite best efforts, 10 million people fell ill from TB and 1.5 million died from the disease in 2018 alone. The End TB Strategy articulates that safer and more effective vaccines, diagnostics and medicines, together with appropriate programmatic innovations are imperative to significantly reduce disease incidence and mortality [3]. Thanks to efforts in the past decade, several drugs, vaccines and diagnostics are under clinical development. As an example, in 2018, the M72/AS01$_E$ vaccine candidate was found to be protective against TB disease in a phase IIb trial among individuals with TB infection [4]. If the findings are confirmed, the vaccine has the potential to transform global TB prevention efforts.

Despite efforts made to date, multiple challenges remain to be addressed in the areas of TB vaccines, diagnostics, medicines, technologies and services, in terms of research, innovation and access [5]. A major challenge is inadequate investment in the development and dissemination of innovative tools and strategies. Although global TB research expenditures increased by 17% in 2018 from 2017, total investments still constituted less than 50% of total funding needs [6]. Funding has historically fallen short of every need in TB research (diagnostics, drugs, vaccines and operational research) [5]. Coupled with weak research infrastructure, low numbers of academic researchers and poor links between national programmes and research institutes, this has slowed the pace of innovation. In addition, the complexity and variability of regulatory processes for reviewing research protocols and new health products, together with barriers in data and patent information sharing practices within or between countries and institutions, adds another layer of constraint to the research process. Member States requested that the World Health Organization (WHO) develop a global strategy for TB research and innovation, based on key steps that countries and non-state actors can undertake to address the above mentioned challenges [7]. The strategy was developed drawing on multiple consultations with Member States, scientists, funders, the private sector, civil society and partners; it was subsequently adopted with a resolution in a written silence procedure, during the 73rd World Health Assembly in August 2020 [8]. It comes at an opportune time when the COVID-19 pandemic has exposed several needs for innovation in the efficient provision of TB prevention and care services.

The global strategy aims to support efforts by governments and other partners to accelerate TB research and innovation, and to improve equitable access to the benefits of research, by setting clear objectives and recommendations, as highlighted below:

1) *Create an enabling environment for high-quality TB research and innovation* by streamlining and harmonising regulatory processes to enable efficient review of research protocols and health products, strengthening public–private partnerships, increasing the number and capacity of health researchers, and integrating civil society's expectations, needs, interests and values into the research process.
2) *Increase financial investments in TB research and innovation* in keeping with the commitments made during the 2018 political declaration of the United Nations General Assembly high-level meeting on

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Member States have adopted the global strategy for TB research and innovation through a written silence procedure of the 73rd World Health Assembly to accelerate TB research and innovation, and to improve equitable access to the benefits of research https://bit.ly/36dyVmB

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TB [9], for example by setting a target contribution for TB research, or by initiating or participating in innovative and collaborative financing mechanisms.

3) *Promote and improve approaches to data sharing* by developing or strengthening a policy of open access to and open data for publicly funded scientific research; promoting transparency in the public disclosure of clinical trial data; establishing or strengthening national health information and vital registration systems, promoting searchable patent databases; and fostering voluntary technology transfer policies that enable the development and diffusion of knowledge.
4) *Promote equitable access to the benefits of research and innovation* by strengthening existing global access initiatives for innovations in TB prevention and care; developing trade rules that help motivate both affordable access and innovation simultaneously; and ensuring the availability of the most recent guidelines and quality-assured tools at all levels of the healthcare system.

Translating these objectives into effective and appropriate actions nationally will likely require the development of an actionable and well-resourced national strategy or roadmap for TB research that is framed around country needs and context. Systematic monitoring and evaluation is also needed to ensure that the necessary investment and policy changes are being made and implemented, and to track whether the implemented policies are having impact. WHO's multisectoral accountability framework to accelerate progress to end TB [10] presents an opportunity to monitor progress; and to learn from the exchange of experience and good practice across countries. Ultimately, the prerequisite for success is a unified and aligned response in which national and international partners and affected communities support Member States by committing to the investments and partnerships necessary for accelerating innovation.

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