

The Bill & Melinda Gates Foundation and Wellcome are investing in the development of a new tuberculosis vaccine

Context

On 1 July 1921 the anti-tuberculosis (TB) vaccine BCG (Bacille bilié de Calmette et Guérin) was administered to a human being for the first time. A baby born into a family with TB was given the vaccine orally and did not develop the disease. Numerous large-scale clinical studies subsequently conducted revealed a 90% efficacy rate against the deadly form of TB in newborns. The vaccine was then distributed worldwide. It is currently the most widely used vaccine in the world and the oldest still in use.

It should be noted, however, that BCG is currently the only licensed vaccine against tuberculosis. However, according to the World Health Organization (WHO), [while it is moderately effective in preventing severe forms of tuberculosis in infants and young children, its protection is insufficient for adolescents and adults, who account for almost 90% of transmissions of the disease worldwide.](#)

Pharmaceutical giant GlaxoSmithKline (GSK) has recently developed the initial phases of a promising new vaccine. Called M72/AS01E, this new TB vaccine, which has been in development for 100 years, proved to be 50% effective in Phase 2b trials in 2018. However, GSK has now decided not to invest in the further large-scale trials required to obtain a license, citing a lack of market opportunity. In other words, there would be no 'economic interest' in saving millions of lives.

Why do we need to tackle TB?

Tuberculosis is a serious infectious disease that affects millions of people worldwide. mainly in low- and
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A few important facts about tuberculosis.

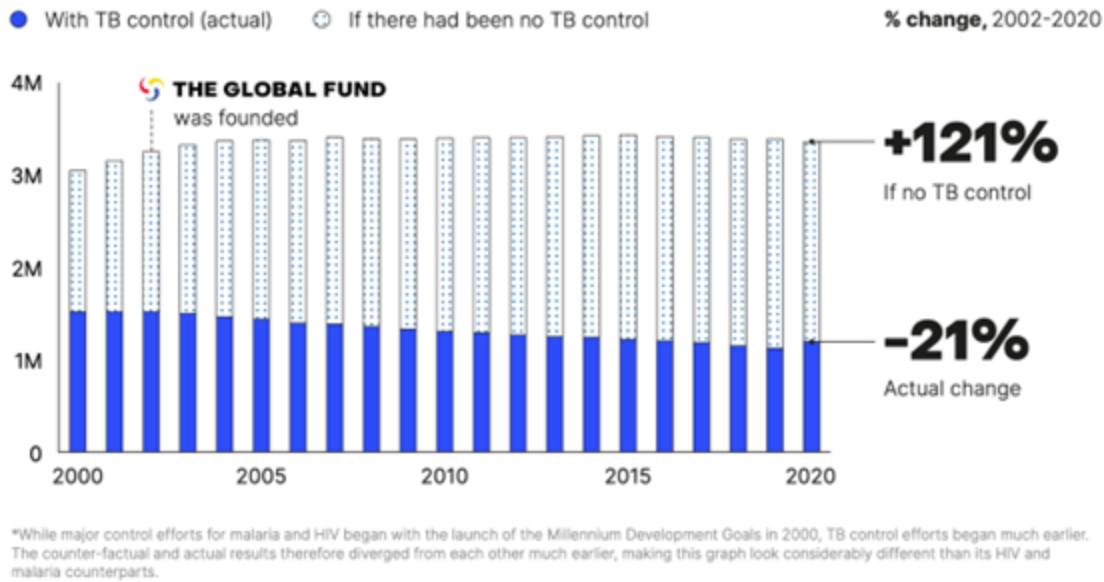
- A total of 1.6 million people died of tuberculosis in 2021 (187,000 of whom also had HIV infection). Worldwide, tuberculosis is the thirteenth leading cause of death and the second leading cause of death due to an infectious disease, behind COVID-19 (and ahead of AIDS).
- According to estimates, 10.6 million people worldwide will have developed tuberculosis by 2021. This includes 6 million men, 3.4 million women and 1.2 million children. Tuberculosis is present in all countries and in all age groups. However, it is a preventable and treatable disease.
- Multidrug-resistant tuberculosis (MDR-TB) remains a public health crisis and a threat to health security. Only around a third of people with drug-resistant tuberculosis had access to treatment in 2021.
- It is estimated that the diagnosis and treatment of tuberculosis saved 74 million lives between 2000 and 2021.
- US\$13 billion will be needed each year for the prevention, diagnosis, treatment and care of tuberculosis to reach the global target agreed at the 2018 United Nations High-Level Meeting on Tuberculosis.
- Ending the tuberculosis epidemic by 2030 is one of the health targets in the United Nations' Sustainable Development Goals.

Source :

<https://www.who.int/fr/news-room/fact-sheets/detail/tuberculosis>

The situation would have been even more dramatic without the investments of the Global Fund. In fact, according to the [2022 Results Report](#), in countries where the Global Fund invests, the number of deaths attributable to TB (excluding people living with HIV) has fallen by 21%.

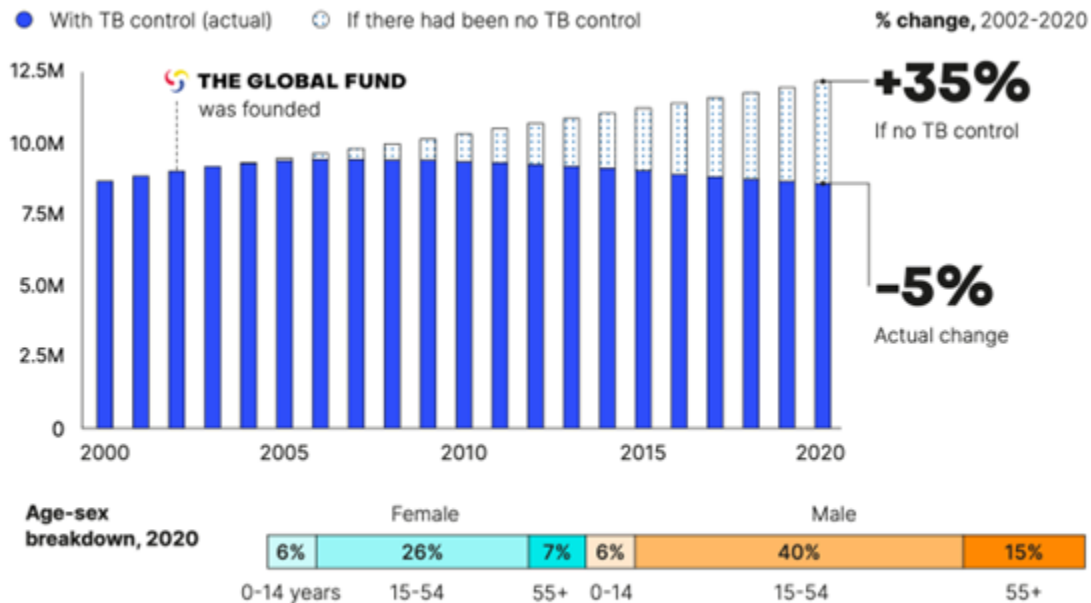
Figure 1. Trends in TB deaths (excluding HIV-positive)* in countries where the Global Fund invests



Source: Global Fund 2022 Results Report (p. 33)

Moreover, the number of new TB cases (all forms) has fallen by 5% between the establishment of the Global Fund in 2002, and the year for which data are most recently available, 2020.

Figure 2. Trends in new TB cases (all forms) in countries where the Global Fund invests



The TB burden estimates are from the WHO Global Tuberculosis Report 2021. The estimation of "no TB control" trends for TB deaths from WHO and for new TB cases is based on the assumption of a constant trend in new TB cases since 2000.

Source: Global Fund 2022 Results Report (p. 33)

The importance of a new, effective TB vaccine

On 28 June 2023 [the Bill & Melinda Gates Foundation and the Wellcome Trust jointly announced](#) they would provide \$550 million to fund a Phase 3 clinical trial of a new TB vaccine. The vaccine, called M72/AS01E, is the first new TB vaccine to be developed for 100 years. The clinical trial will assess the vaccine's effectiveness in preventing the progression of latent tuberculosis infection to pulmonary tuberculosis. Here are a few arguments to support the importance of such a vaccine:

- **Prevention:** An effective vaccine against TB would make it possible to prevent the disease and reduce the number of deaths caused by TB. It would also prevent transmission of the disease, particularly in areas with a high TB incidence, notably in South Asia and Africa.
- **Cost-effectiveness:** An effective vaccine against TB would be a profitable investment for governments and public health organizations. It would reduce the cost of treating the disease and prevent TB-associated complications, such as multidrug-resistant TB.
- **Strengthening health systems:** Developing an effective TB vaccine requires investment in research and development, which can help to strengthen health systems in Africa. This can help improve countries' ability to meet the health needs of their populations.
- **Impact on poverty:** TB is often associated with poverty and unfavorable socio-economic conditions. An effective TB vaccine could help to reduce poverty by preventing the disease and improving the health of the most vulnerable populations.

"A 75% effective vaccine could prevent up to 110 million new cases of tuberculosis and 12.3 million deaths. The study also showed that every dollar invested in a vaccine that is 50% effective is likely to generate a return on investment of \$7 through avoided healthcare costs and increased productivity.

Source : <https://www.who.int/fr/news/item/17-01-2023-who-announces-plans-to-establish-a-tb-vaccine-accelerator-council>

All in all, the development of an effective TB vaccine is crucial to preventing the disease, reducing treatment costs, strengthening healthcare systems, reducing poverty and improving the health of the most vulnerable populations. This is why the joint initiative of the Bill & Melinda Gates Foundation and the Wellcome Trust is so welcome.

The importance of the African Medicines Agency

Notwithstanding the above, GSK's refusal to continue the clinical trials on the M72/AS01E vaccine, given its promotional nature, only serves to highlight the greed of certain pharmaceutical companies. Above all, it is a reminder, if one were needed, of the need for developing countries, particularly those on the African continent, to increase the budgets devoted to health in general and to medical research and development (R&D) in particular. For example, it is more important than ever for these countries to support the

deployment and activities of the brand-new African Medicines Agency (AMA).

Clearly, when we know that “[the pharmaceutical industry favors the development of medicines](#)” [blockbusters “guaranteeing high profits in the long term rather than vaccines providing immunization against diseases”](#) – many of which are found in developing countries where purchasing power is low ; when we know that the 54 drugs that could control 90% of African diseases are not licensed or patented – and could therefore be produced in Africa – it seems all the more urgent for the continent to build and direct its R&D according to its needs and priorities.

In fact, according to the [African Centre for Disease Control and Prevention \(CDC Africa\)](#), the African continent can only guarantee its health security if – among other things – it manufactures at least 60% of its vaccine requirements by 2040. In this context, rather than giving an African focus to research, it is above all a question of pooling the skills that are fragmented and scattered across the continent and providing the national agencies with the resources they need to carry out their missions. The AAM could be an excellent vehicle for this.

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