

The urgent need for a TB vaccine



Translating science
into global health impact

A vaccine is necessary to end the TB epidemic. IAVI and partners continue to make strides to reach this goal.

The world's biggest infectious killer

Tuberculosis (TB), declared a public health emergency by the World Health Organization (WHO) in 1993, remains a major global health threat. TB kills more people than any other single infectious disease, and today, **4,000 die of TB every day**. TB is one of the major contributors to the global burden of antimicrobial resistance, with multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) both on the rise. TB is primarily a disease of poverty, with over 90% of TB cases occurring in developing and emerging economies and imposing an enormous socio-economic burden on patients, families, and communities. It has become clear that we are far off course to reach the WHO goal to end TB by 2035. This cannot be achieved without new vaccines, diagnostics, and drugs.

Limited impact of existing vaccine

There is only one TB vaccine, bacillus Calmette-Guérin (BCG), which is nearly 100 years old. The vaccine has efficacy in protection against severe tuberculosis disease, such as TB meningitis and miliary TB, in infants and young children, but offers variable and mostly poor protection against lung disease in adolescents and adults. The latter populations are responsible for spreading TB in the community. To interrupt transmission, new and more effective vaccines that target adolescents and adults are therefore needed.

Reaching the WHO End TB Strategy targets of a 95% reduction in TB mortality and a 90% reduction in TB incidence, worldwide, by 2035, will require a new vaccine that is effective at preventing adult tuberculosis.

TB by Numbers



10.0 million
people developed TB disease
in 2018



1.5 million
people died of TB disease
in 2018



25% of people
globally may be infected
with TB



\$1.3 billion
funding gap for TB



862,000 new TB cases
among people living with HIV
in 2018

Sources available at iavi.org/fact-sheets-sources

TB R&D shortfall

TB R&D has been chronically underfunded in relation to the impact of TB upon global health, even though it causes more deaths than HIV/AIDS and malaria combined. The Declaration of the 2018 UN High-Level Meeting on Ending TB included the Stop TB Partnership's call for TB R&D investment to be increased to meet the funding shortfall of \$1.3 billion, whilst also noting the importance of developing new and effective vaccines. Meanwhile, the WHO has concluded that 'targets for 2035 cannot be met without intensified R&D.'

TB vaccine development is at a critical juncture

We are just now making breakthroughs in clinical efficacy trials, animal models, and new candidates that will inform the next generation of research and clinical development. If these advances are slowed, the world is likely to lose 10-20 years of progress toward a successful vaccine. We now need to accelerate the development of TB vaccines: we need to confirm the results of the recent studies, test TB vaccines in broader populations, plan for licensure trials, and develop roadmaps to ensure prompt and equitable access to future TB vaccines.

New TB vaccines on the horizon

Recent significant trial results suggest that new effective TB vaccines can be developed in the coming decade if the appropriate investments are made. Moreover, there are ongoing efforts across the TB research community to broaden the diversity of immune responses through innovative and emerging platforms, such as nucleic acid vector approaches, antibody mediated protection, and improved protein adjuvant combinations. Funders need to invest in all phases of research and develop a plan for access to bring the first of a new generation of safe and effective TB vaccines to the people who need them most.

No human disease has ever been eradicated without a vaccine. We need one to end TB.

Why do we need a vaccine to end the TB epidemic?

- Vaccines typically provide long-lasting protection.
- Vaccines could eliminate adherence and stigma problems associated with TB treatment.
- Vaccines would reduce the incidence of MDR- and XDR-TB.
- Vaccines would prevent TB transmission, having a significant impact on the epidemic.

Global TB Vaccine Pipeline

Overall pipeline



15+ trials

whole-cell, subunit, and viral-vector candidates in all phases

Late-phase Efficacy Trials



7 trials

whole-cell and subunit in phase 2 proof-of-concept to Phase III

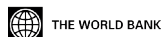
IAVI Clinical Trial Collaborations



3 trials

whole-cell and subunit in Phases II and III

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