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Short Communication

Development of Novel Childhood and Adult Tuberculosis Vaccines

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Approximately, one-third of the world's population are infected with *Mycobacterium tuberculosis (M.tb.)*. In 2017, an estimated 558,000 persons developed drug-resistant tuberculosis (DR-TB), 82% of which were multidrug-resistant tuberculosis (MDR-TB); and 230,000 deaths were caused by drug-resistant TB disease. Tuberculosis (TB) causes substantial economic burden in addition to enormous human suffering and one of the major drivers of global inequity. Bacille Calmette-Gue´rin (BCG), an attenuated strain of *Mycobacterium bovis* that the loss of virulence of this strain is caused by the deletion of the RD-1 locus that encodes nine genes including a 6-kDa early secreted-antigen (ESTAT-6) and a 10-kDA cultured filtered protein (CFP-10). Both are proteins secreted by the Snm secretion system and are considered essential virulence factors leading to *M.tb*. pathogenesis, demonstrating that they may be good vaccine targets. Whereas BCG is partially efficacious at protecting infants and young children, it is poorly protective against pulmonary TB adolescents and adult. By 2035, the World Health Organization (WHO) End TB Strategy targets of a 90% reduction in TB incidence and a 95% reduction in TB mortality, this will require a novel vaccine that is effective in adults who have latent *M.tb*. infection as well as who have not yet been infected with *M.tb*. Vaccines also offer the best chance to contain the accelerating spread of multidrug-resistant TB. Currently, the TB vaccine candidate pipeline incorporates various vaccine platforms including vectored subunit vaccines, adjuvanted proteins, and whole cell vaccines. The TB vaccine candidates are being developed for early life immunization as BCG replacement, as BCG boosters, prevention of TB in adolescents and adults, as immunotherapeutic adjuncts to drug therapy intended to reduce treatment duration, and for vaccination of TB patients after treatment to prevent disease recurrence. The WHO Initiative for Vaccine Research has announced that the development of novel TB vaccines is a priority, based on potential value of WHO involvement, technical feasibility assessment, and a high unmet medical need via PDVAC consultation. The PDVAC also called for the development of a document highlighting WHO preferred Product Characteristics (PPC) for novel TB vaccines.

Recently, a studying TB vaccine candidate " M72/AS01E ", conducted in Zambia, South Africa, and Kenya for nearly 20 years was identified to be significantly protective against TB disease in a Phase IIb trial in persons with evidence of latent TB infection. The point estimated efficacy of this vaccine was 54% (90% Confidential Interval, 14 - 75; probability = 0.04), over approximately two follow-up years. If all goes well, the novel TB vaccines should reach people who most need them by about 2028.

In conclusion, it will be imperative for any novel TB vaccine to be affordable, safe, and accessible to individuals in low- and middle-income countries (LMICs). Novel TB vaccines should be safe for use in human-immunodeficiency-virus infected persons. In terms of clinical significance and strength of evidence, unprecedented in decades of novel TB vaccine research, particularly the study results of M72/AS01E vaccine trial constitute a major scientific breakthrough.

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