

Lessons from accelerated Covid-19 vaccine development for TB

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1. Background

- **Rapid development of Covid-19 vaccines vs slow progress in tuberculosis (TB) vaccine research:** 14 Covid-19 vaccines approved within 24 months of the pandemic being declared, no new TB vaccines have been licensed since BCG vaccine in 1921, despite TB killing over a million people annually for the past decade
- The BMGF-sponsored Collaboration for TB Vaccine Discovery's Epidemiology, Modelling, and Trial Designs Research Community sought to explore which **lessons from Covid-19 vaccine development** can be applied to accelerate TB vaccine progress, particularly **in clinical trial design and regulatory approvals.**

2. Methods

- **Expert interviews;** using purposive, convenience-based sampling; including directors of research programs, principal investigators of Covid-19 studies, members of regulatory bodies
- Data analysed using **Braun and Clark's Thematic Analysis**, contextualised within review of the current state of TB vaccines, and literature on Covid-19 clinical trials and regulatory approvals
- Study approved by the University of KwaZulu-Natal Biomedical Research Ethics Committee

3. Results

Fifteen interviews were conducted between February and May 2024. Three dominant themes were generated.

Covid-19 and TB fundamentally incomparable?

Covid-19	TB
<i>Clinical course</i>	
develops within days to weeks post-infection	develops in months to years post-infection, highly variable clinical course
<i>Causative organism</i>	
29.9kB genome with 12 expressed genes, and single spike protein	4.4 million base pairs encoding over 3906 protein genes, no consensus on the best target antigens
<i>Sociopolitical context</i>	
novel pathogen, affected people in the Western world, where global financial resources most concentrated	ancient pathogen, affecting under-resourced countries "TB is a disease of the poor."

Planning for success

- **Balancing flexibility and harmonization;** respondents emphasised the value of adaptive trial designs and of standardised clinical endpoints
- **Data relevant for policy;** safety and efficacy data are not always sufficient to inform policy
- **Nurturing global collaboration;** reliance approaches facilitate more efficient and better science
- **Systems for post rollout monitoring;** the clinical trial is but the first step

Costs of accelerated Covid-19 vaccine development



- Covid-19 vaccine development was de-risked for private developers by generous allocation of public funds



- Covid-19 research was prioritized above all else
- Extremely labour intensive; costs to human wellbeing, stress, burnout



- The pace of development left us with poorly comparable data across products and platforms

4. Conclusion

Key areas for future focus:

1. **Cross-disciplinary** learning and innovation, especially across pathogens and diseases
2. Strong **advocacy** to secure necessary resources and developing strategies to mitigate the associated costs
3. **Planning** is essential; we must establish robust systems for collaboration and efficiency

By embracing these lessons and strategies, we can accelerate the development of TB vaccines and enhance our preparedness for future pandemics.

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