



Epidemiology, Modelling, and Trial Designs CTVD RC

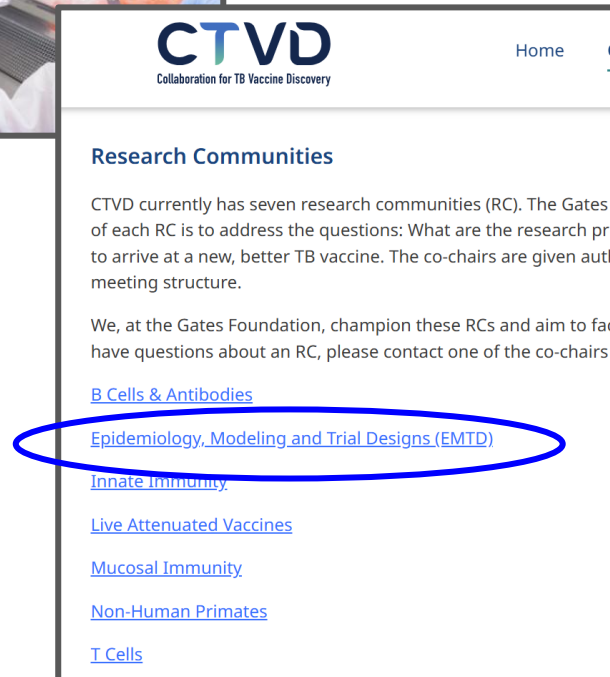


richard.white@lshtm.ac.uk for all



Epidemiology, Modelling, and Trial Designs Research Community

- is part of Collaboration for TB Vaccine Discovery



- GF funded
- Other RC's more upstream - **Discovery** to development
- EMTD focus more downstream - **Development** to implementation
 - Epi, modelling & trials
 - Not implementation but *'Implementation aware'* development eg highlight data to collect in trials, useful for implementation

Epidemiology, Modelling, and Trial Designs Research Community

- focus

'Think Tank' will focus of accelerating development of new TB vaccines

1) Epidemiological considerations for new TB vaccine clinical trial design, eg

- evaluation/selection of trial endpoints
- evaluation/selection of trial populations

1) The potential impact and cost-effectiveness of new TB vaccines, eg

- evaluation of different types of vaccines/vaccination strategies

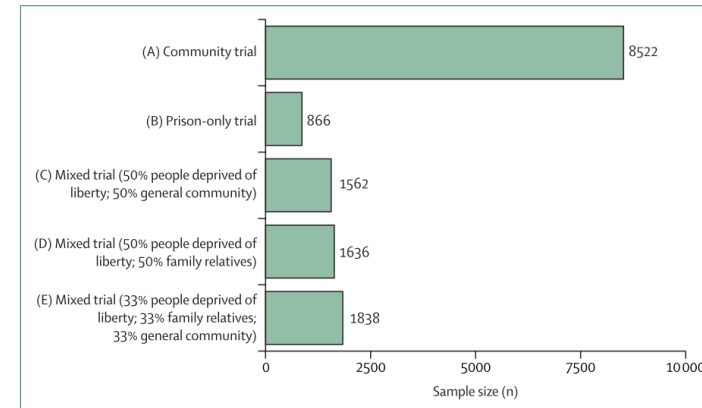
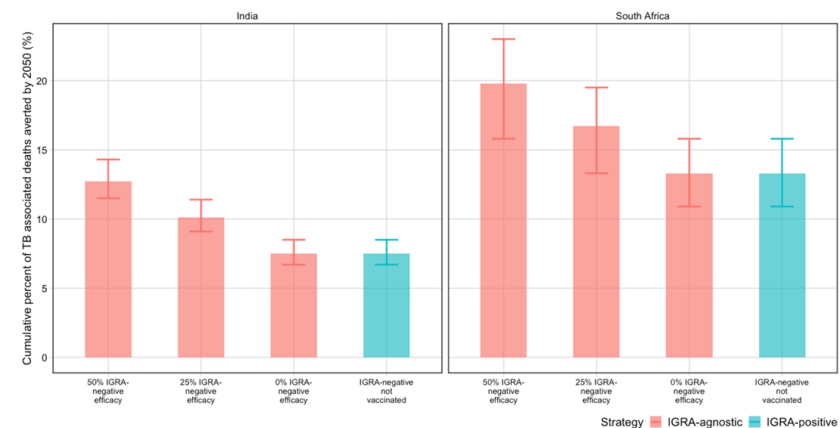


Figure: Sample size estimates for tuberculosis prevention-of-disease vaccine trials



Epidemiology, Modelling, and Trial Designs Research Community

- who we are



Expertise

- Mostly academics
 - epidemiologists, immunologists, statisticians, modellers, ...
- Trialists
- Sponsor
- Industry
- Advocate
- Supported by Kristin and Alex at GF
- No direct link to policy, unlike WHO TAG
 - But aims to generate evidence that will be useful for policy

Epidemiology, Modelling, and Trial Designs Research Community

- how & general activities

- Brainstorm new ideas/generate new knowledge, for ideas that we think have value
- Disseminate them to support decision making (by developers, funders, implementers, regulators, ...)
- Support to trial sponsors to design trials
- Support other RCs (mostly discovery)
- Think pieces (egs next)
 - how might accelerate clinical development
 - special populations
 - impact of types of new vaccines/strategies
- Starting to work with TAG to produce lay summaries/ policy briefs



Epidemiology, Modelling, and Trial Designs Research Community

- a few think pieces...

Personal View

Implications of subclinical tuberculosis for vaccine trial design and global effect

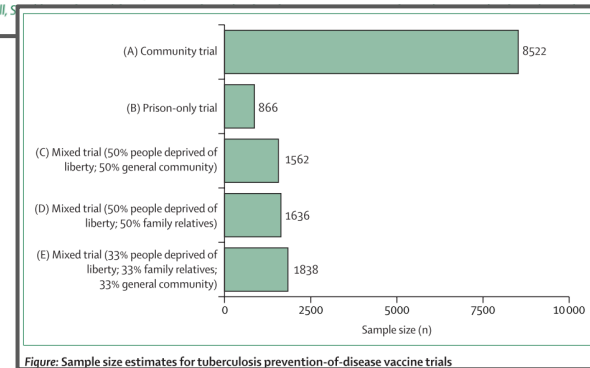
Gavin J Churchyard, Rein M G J Houben, Katherine Fielder, Marcel Behr, Alberto L Garcia-Basteiro, Emily B Wong, Mark Frank Cobelens, Richard G White

Figure 2: Tuberculosis screening before enrolment, during, and at the end of follow-up

Personal View

The participation of people deprived of liberty in tuberculosis vaccine trials: should they be protected from research, or through research?

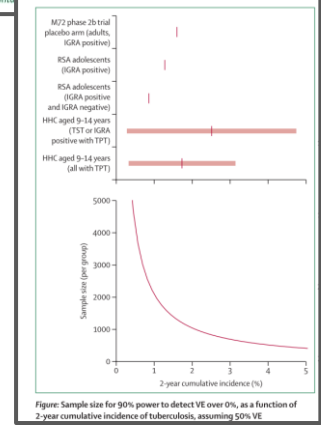
Jason R Andrews, Salome Charalambous, Gavin Churchyard, Frank Cobelens, Carlos Fernández-Escobar, Mike Frick, Willem Hanekom, Mark Hatherill, Philip C Hill, Alberto L Garcia-Basteiro



25TLGH1231
Health Policy
Emma F
This version saved: 09/22, 24 Apr 26

Inclusion of young adolescents in policy development for new tuberculosis vaccines

Mark Hatherill, Rebecca A Clark, Leonardo Martinez, Andrew L Fiore-Gartland, Alberto L Garcia-Basteiro, Gavin J Churchyard, Molebogeng X Rangaka, Marcel A Behr, Thomas Evans, Vidya Mave, Philip C Hill, Willem A Hanekom, Frank Cobelens, Richard G White, and The Pediatric TB Consortium



Personal View

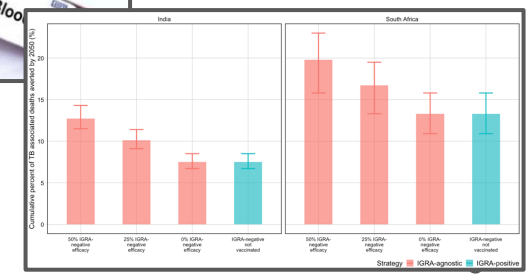
Evidence required to evaluate the use of bacteriologically confirmed asymptomatic tuberculosis disease as a primary endpoint in prevention of tuberculosis disease vaccine licensure trials

Richard G White, Gavin J Churchyard, Katherine C Harton, Andrew Fiore-Gartland, Marcel A Behr, Rebecca A Clark, Frank Cobelens, Joel D Ernst, Hanif Esmail, Alberto L Garcia-Basteiro, Emily B Wong, Mark Frank Cobelens, Rein M G J Houben, Lele Rangaka, Helen Sutherland, Willem A Hanekom, Philip C Hill, Rudzani Muloiwa, Puck T Pelzer, Mark Hatherill, Philip C Hill, Rudzani Muloiwa, Puck T Pelzer, Rein M G J Houben, Lele Rangaka, Helen Sutherland

Figure 1: Estimated number of trial endpoints in the control group of a prevention-of-disease vaccine trial in a high disease-burden setting

Global and country policy makers

- 1 Accelerating TB Vaccine Development: Lessons from COVID-19 Clinical
- 2 Trial Design and Regulation
- 3 Authors
- 4 Yumna Moosa¹, Willem Hanekom^{1,2}



(unpublished)

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