

## Challenges in recruiting neonates for a phase III TB vaccine trial and mitigations taken: Lessons learned for community engagement in Mbeya, Tanzania

**Doreen Ibrahim Pamba**<sup>1</sup>, Anange Lwilla<sup>2</sup>, Lonze Ndelwa<sup>2</sup>, Lucas Maganga<sup>2</sup>, Nickson Pancras<sup>2</sup>, Oliver Lyoba<sup>2</sup>, Faith Mlagalila<sup>2</sup>, Elimina Siyame<sup>3</sup>, Lilian Tina Minja<sup>2</sup>, Issa Sabi<sup>2</sup>

<sup>1</sup>Research Monitoring and Evaluation, National Institute for Medical Research, Mbeya, Tanzania; <sup>2</sup>National Institute for Medical Research-Mbeya Center, Mbeya, Tanzania; <sup>3</sup>Mbeya College of Health and Allied Sciences, Mbeya, Tanzania

**Introduction:** The priMe TB trial is a phase III clinical trial evaluating the safety and efficacy of a novel tuberculosis (TB) vaccine candidate among neonates in 5 African countries. Protection with the available licensed TB vaccine thus, novel improved vaccines are needed. Development of new TB vaccines requires retained participation in trials. Being the first neonatal TB vaccine trial in Tanzania, bottlenecks were encountered during recruitment. We describe challenges experienced in recruiting neonates and mitigations adopted to attain recruitment and retention targets set within the priMe TB trial.

**Methods:** 547 neonates were recruited from a maternity hospital over 10 months. We held semi-structured in-depth interviews in May 2024 with 3 medical doctors, 2 nurses and 1 community engagement officer who were part of the research team conducting the priMe trial in Mbeya, Tanzania. Data were analyzed by content analysis using ATLAS.ti Web.

**Results:** Challenges included; lack of community awareness about TB vaccine research, attributing COVID-19 vaccination to the candidate TB vaccine, misconceptions about vaccine research, family disputes arising from prevailing patriarchal values and religious beliefs impeding participation. To attain recruitment targets, different strategies were adopted namely; support from efficient recruitment team, regular sensitization meetings with communities and community advisory board members, frequent engagement of community leaders, participant retention meetings, minimizing clinic waiting times and support from health providers in routine facilities.

**Conclusion:** sustained engagement of community stakeholders and health providers in non-research facilities is salient for successful neonatal TB vaccine research. To minimize misconceptions and optimize participation, community sensitization on TB vaccine research prior and during implementation of trials is necessary.

Clinical trial identification: NCT04351685

### Funding Sources

None

### Conflicts of Interest

None

