Radiant-Moms Study: Exploring the Feasibility, Acceptability, and Demand for Shorter TB Treatment Regimens in Pregnant and Breastfeeding People

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BACKGROUND

- Tuberculosis (TB) risk greatly increases during and immediately after pregnancy.[1]
- Optimizing the care of pregnant and breastfeeding people (PBP) should be a global priority, yet PBP are often excluded from TB clinical trials resulting in limited access to novel treatment options.[2]
- The World Health Organization now recommends a new, shorter TB treatment regimen as an effective option for adults and adolescents with drug-sensitive TB (DS-TB) based on results from clinical trials.[3,4]
- However, PBP were excluded from these clinical trials so this new regimen is not recommended for their use.
- As a result, PBP are treated for DS-TB with older, longer TB treatment regimens.
- Limited information exists on the perspectives of PBP and health care providers (HCP) in TB-endemic countries on whether to take or recommend new TB treatment regimens to PBP and if to include them in TB clinical trials.

METHODS

- A link to a brief anonymous online survey was distributed globally to key stakeholders at clinical research sites funded by NIH and CDC.
- The survey collected information on demographics, past TB disease and treatment experiences, and feasibility, acceptability, and perceived demand for the new, shorter TB treatment regimen for PBP among stakeholders.
- REDCap database on a secure server was used to collect survey data.
- 5-point Likert Scale ranging from strongly disagree to strongly agree was used to capture participant attitudes.
- We categorized agreement as strongly agree/agree and disagreement as strongly disagree/disagree.
- SAS was used to summarize response data and compare attitudes and preferences between HCP/researchers and community stakeholders.

PROJECT AIMS

- Radiant-Moms aims to explore the feasibility, acceptability, and potential demand for shorter TB treatment regimens for PBP and their inclusion in TB clinical trials.

STAKEHOLDERS AGREE!
PREGNANT AND BREASTFEEDING PEOPLE SHOULD BE INCLUDED IN TUBERCULOSIS CLINICAL TRIALS

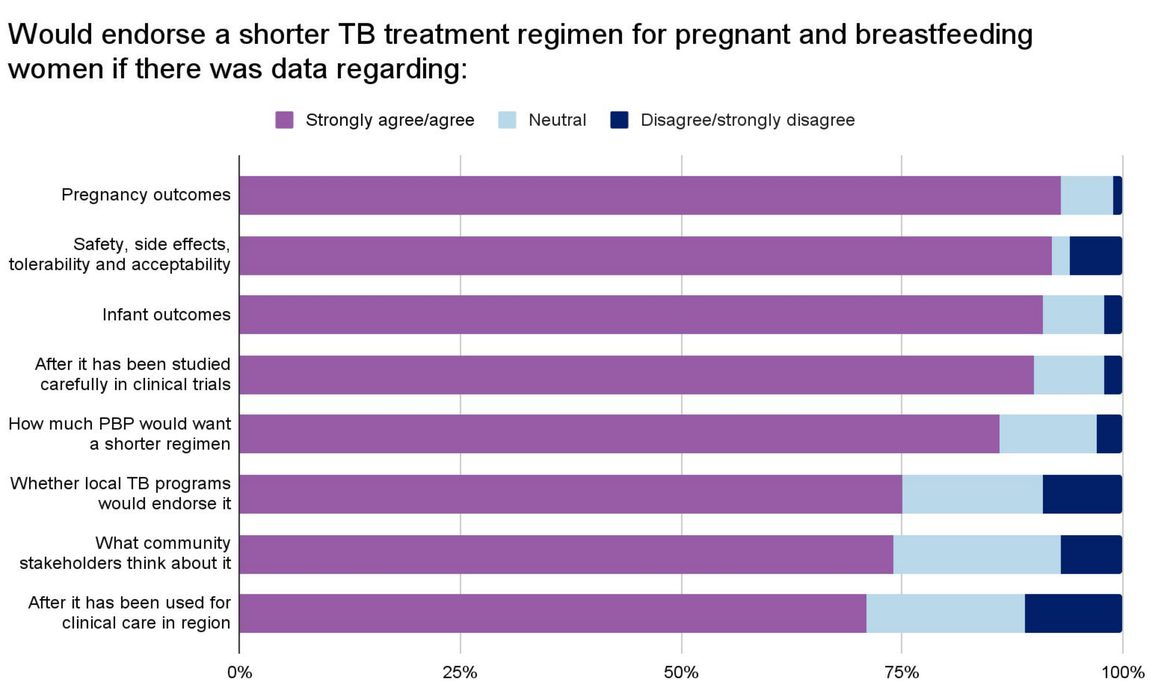
RESULTS

- 125 HCP, researchers, and community stakeholders from more than 20 countries completed the survey (Table 1).
- There was broad consensus among HCP/researchers and community influencers, with 91% of HCP/researchers and 86% of community influencers agreeing that identifying new TB treatment options for PBP represents a significant research gap.
- Only 29% of all stakeholders agreed that current treatment options for DS-TB in PBP are adequate.
- Overall, 89% of stakeholders agreed that the new, shorter regimen should be evaluated in PBP and 72% agreed that it should be offered to PBP.
- The majority of stakeholders would endorse a shorter treatment regimen for PBP if there was data to support its implementation (Figure 1).

Table 1. Study Sample Characteristics

Sample size (N)	125	Median age (IQR)	35-54
Assigned female sex at birth	66%	Median years working in TB (IQR)	5-20
Country of work (top 4):		**Type of stakeholder:**	
South Africa	30%	Healthcare professional	37%
U.S.	11%	Community influencer	34%
India	8%	Researcher	27%
Kenya	8%	Other	2%
Ever treated for TB	18%	Known women with TB during pregnancy	74%

Figure 1. Stakeholder Consensus on the Necessity of Data to Support Shorter TB Treatment Regimens



CONCLUSIONS AND NEXT STEPS

- Results revealed a consensus among stakeholders that current TB treatment regimens for PBP are inadequate.
- Stakeholder agreement emphasizes the need for data to endorse a shorter regimen for PBP and highlights the importance of inclusion of PBP in TB clinical trials.
- Qualitative interviews will be held in South Africa and the Philippines to further explore attitudes and preferences regarding the inclusion of PBP in TB clinical trials.
- This data will inform the design of a discrete choice experiment to be conducted among stakeholders and provide support for the inclusion of PBP in TB clinical trials.
- Findings from the study will ultimately help to inform policy and improve clinical care for this priority population.

COMPETENCIES AND STUDENT CONTRIBUTIONS

Competencies	How did we do this?
Appraise epidemiological literature critically in a defined problem area using advanced bibliographic and informatics resources for purposes of evaluation, summary, and translation.	Researched and developed a clinical trial database, including completed, ongoing, and planned TB therapeutic and vaccine trials to explore inclusion trends for PBP.
Analyze public health problems in terms of magnitude; person, time, and place; and the distribution and determinants of both chronic and infectious diseases; and principles of disease prevention in different populations.	Organized, cleaned, and analyzed anonymous survey data using Excel and SAS.
Select quantitative and qualitative data collection methods appropriate for a given public health context.	Assisted in the preparation of a protocol, informed consent forms, and data collection instruments for a forthcoming discrete choice experiment.

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