

# Community Consensus and Call to Action on Inclusion of Pregnant and Breastfeeding Women and Persons in TB Vaccine Trials

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## Background

Each year 200 million people become pregnant and face pregnancy-associated immune changes that increase their risk of TB during pregnancy and the postpartum period. Yet, vaccine trials routinely exclude pregnant and lactating populations.

As a result of this exclusion, pregnant and breastfeeding women and persons are regularly made to wait years for data on safety of novel TB treatment and vaccines in the pregnant and post-partum period. This represent millions of missed opportunities for potential intervention or vaccination as part of the regular engagement with the healthcare system during pregnancy.

## Methods

In October 2023, 16 representatives with direct lived experience or experience living and working in communities with experience related to TB in pregnancy from 13 countries and 5 regions met to develop a community consensus on the inclusion of pregnant and breastfeeding women and persons in TB treatment and vaccines research.

Over the course of four days, community representatives met with clinicians and scientists leading TB studies to discuss the relationship between TB and pregnancy and scientific position on the exclusion of pregnant persons from TB vaccine clinical trials. On the final day, the community convened in working groups to develop a community consensus on inclusion of pregnant persons in TB clinical trials.



Community representatives, panelists, and civil society participants in Washington, D.C., October 2023

## Results

Four points emerged as the basis of the community consensus statement regarding pregnancy and vaccines:

- 1) The risks of each vaccine candidate should be assessed independently and individually;
- 2) conducting preclinical safety studies earlier in vaccine development is necessary to enable inclusion of pregnant persons in late-stage trials;
- 3) pregnant persons can weigh potential risks and benefits of participating in research and should be empowered to do so; and
- 4) there is little justification for excluding breastfeeding people, who should be considered separately from pregnant populations, from vaccine trials.

“ *The current failure to investigate vaccine safety in pregnancy during efficacy trials represents a missed opportunity to identify safe and effective vaccines to protect women and persons during pregnancy, the postpartum period, and/or beyond.* ”

The community consensus acknowledged that failure to include pregnant persons in TB vaccine research represents a breakdown in the provision of equitable healthcare. Pregnancy is a period of regular engagement with the healthcare system and vaccinating in this period is likely to confer protection into the postpartum period (when risk TB disease is highest) and beyond. For TB vaccines to be made available to pregnant populations, pregnant persons need to be included in Phase III clinical trials. Failure to do so represents a form of sex-based discrimination and misogyny that seeks to protect women and persons *from* research not *through* research.

## Conclusion

Community representatives issued calls to action to researchers, funders, policymakers, and other stakeholders to work towards a new approach to TB vaccine R&D – one that assumes inclusion of pregnant and breastfeeding persons, extending to all the right to participate in the advancements of science.

“ *Continued failure to include pregnant and breastfeeding women and persons in the research agenda leaves pregnant and breastfeeding women and persons to shoulder the risks of older, untested treatments and without the prospect of protective immunity during pregnancy and the postpartum period through vaccination.* ”

- 📣 TB vaccine researchers and clinicians must shift the paradigm on the inclusion of pregnant and breastfeeding persons in vaccine trials, starting with assessing the risks of inclusion in partnership with communities and affected individuals.
- 📣 TB vaccines research must move to a model that assumes inclusion of pregnant women and persons in clinical trials and conducts safety studies to support enrollment of pregnant participants in Phase III clinical trials to realize it.
- 📣 Exclusions should be justified with explicit data to support the decision.
- 📣 Funders and policymakers must enable this shift by actively facilitating and promoting the inclusion of pregnant and breastfeeding persons in vaccine clinical trials.

Accelerating progress towards developing evidence-based interventions for and improved health outcomes among pregnant, postpartum, and breastfeeding women and persons affected by TB demands an urgent shift towards inclusion of pregnant persons in future TB vaccine clinical trials.

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Consensus  
Statement