

## Community consensus and call to action on inclusion of pregnant and breastfeeding women and persons in TB vaccine trials

Ani Herna Sari<sup>1</sup>, **Edna Tembo**<sup>2</sup>, Erin V McConnell

<sup>1</sup>*Rekat Peduli Indonesia, Surabaya, Indonesia;* <sup>2</sup>*Coalition of Women Living with HIV & AIDs (COWLHA), Lilongwe, Malawi;* <sup>3</sup>*TAG, New York, New York, USA*

**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.

**Methods:** In October 2023, 16 representatives of communities with experience related to TB in pregnancy met to develop a community consensus on the inclusion of pregnant and breastfeeding women and persons in TB treatment and vaccines research. The consensus was informed by discussions with clinicians, scientists, and community networks.

**Results:** Four points emerged as the basis of the community consensus statement: 1) the risks of each vaccine candidate should be assessed 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 lactating people, who should be considered separately from pregnant populations, from vaccine trials.

Pregnancy is a period of regular engagement with the healthcare system and vaccinating during pregnancy is likely to confer protection into the postpartum period (when risk of TB disease is highest) and beyond. For TB vaccines to be made available to pregnant populations, they need to be included in vaccines research.

**Conclusion:** From these shared perspectives, 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. This session will discuss the community consensus and calls to action, proposing a path forward for including pregnant and lactating persons in vaccine research.

### Funding Sources

Not applicable

### Conflicts of Interest

None

