Inclusion of pregnant women in TB drug and vaccine research

Update for IMPAACT Network Meeting

26 September 2024

World Health Organization

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Supporting, Mobilizing, and Accelerating Research for Tuberculosis Elimination

SMART4TB Consortium

Outline

- Background to Consensus Process
- Current Activities
- 2025 Consensus Meeting

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Background to Consensus Process

- Current process launched at 2023 meeting co-convened by SMART4TB, WHO Global TB Programme and IMPAACT Network: *A primer on tuberculosis and pregnancy: laying the groundwork for consensus*

- In parallel a meeting was convened for representatives of affected communities to develop their own consensus on the inclusion of pregnant and breastfeeding women in TB research

- Outputs of the meetings included a Community Consensus Statement and a list of key challenges and opportunities in important areas of work to move the field forward

Background to Consensus Process

- Follow-up process to 2023 meeting coordinated by WHO in collaboration with SMART4TB with vital inputs from many partners, including the IMPAACT Network

- Five thematic working groups established:
  - Advocacy
  - Pre-clinical
  - Therapeutics
  - Vaccines
  - Surveillance

- TORs for working groups developed in part from 2023 meeting outputs

Current Activities

Working groups:

- Work groups identifying key ‘asks’ for consideration at 2025 Consensus Meeting
- Working group papers to serve as background documents to support ‘asks’ and lead to peer-reviewed manuscripts
- ‘Technical’ working groups sharing outputs with Advocacy Working Group to support future advocacy efforts

Current Activities

Commissioned reviews:

- Work underway on three commissioned reviews:
  - Systematic review on TB and Pregnancy
  - Review on barriers and facilitators to inclusion of pregnant and lactating women in trials
  - Surveillance funding landscape analysis
- Engagement with working groups and stakeholders during and after completion of work

Current Activities

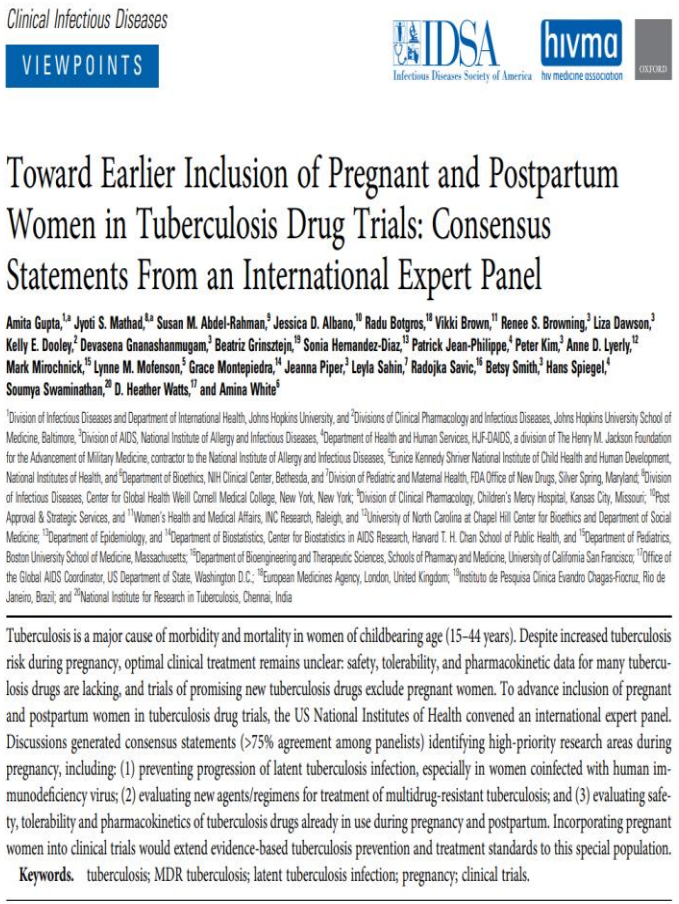
- Regulatory engagement
  - Finalizing document summarizing regulatory issues/questions arising from WGs
  - Panel of ~5 regulatory experts identified for an informal consultation
  - 90 minutes zoom discussion in October with panel and WG members to explore identified issues
  - Meeting summary to feed into WG papers and consensus meeting discussion

2025 Consensus Meeting

- Consensus meeting scheduled for February 25-26, 2025
- Hybrid format – still determining in-person capacity in Geneva
- Main outputs:
    - Meeting report/Consensus statement
    - Call to action
    - Development of peer-reviewed papers from ongoing working group efforts

2025 Consensus Meeting

- Follow up will be critical!



Clinical Infectious Diseases

VIEWPOINTS

Toward Earlier Inclusion of Pregnant and Postpartum Women in Tuberculosis Drug Trials: Consensus Statements From an International Expert Panel

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Tuberculosis is a major cause of morbidity and mortality in women of childbearing age (15–44 years). Despite increased tuberculosis risk during pregnancy, optimal clinical treatment remains unclear: safety, tolerability, and pharmacokinetic data for many tuberculosis drugs are lacking, and trials of promising new tuberculosis drugs exclude pregnant women. To advance inclusion of pregnant and postpartum women in tuberculosis drug trials, the US National Institutes of Health convened an international expert panel. Discussions generated consensus statements (>75% agreement among panelists) identifying high-priority research areas during pregnancy, including: (1) preventing progression of latent tuberculosis infection, especially in women coinfected with human immunodeficiency virus; (2) evaluating new agents/regimens for treatment of multidrug-resistant tuberculosis; and (3) evaluating safety, tolerability and pharmacokinetics of tuberculosis drugs already in use during pregnancy and postpartum. Incorporating pregnant women into clinical trials would extend evidence-based tuberculosis prevention and treatment standards to this special population.

Keywords. tuberculosis; MDR tuberculosis; latent tuberculosis infection; pregnancy; clinical trials.

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