

Ms. Lisa Kaeser, Executive Secretary
Eunice Kennedy Shriver National Institute of Child Health and Human Development
31 Center Drive, Room 2A03, MSC 2425
Bethesda, MD 20892

17 August 2017

Public Comment Re: Federal activities necessary to address gaps in knowledge about how to safely and effectively treat tuberculosis infection and disease in pregnant and postpartum women.

Dear Ms. Kaeser,

As a community of advocates, researchers, and clinicians concerned by the paucity of data available to guide the safe and effective treatment of pregnant and postpartum women with tuberculosis (TB) infection and disease, we submit the following public comment for consideration by the Task Force on Research Specific to Pregnant Women and Lactating Women (the Task Force).

TB affects both mother and the existing pregnancy. It increases the likelihood of poor birth outcomes, including spontaneous abortion, suboptimal weight gain, preterm labor, transmission of congenital TB, neonatal and perinatal mortality, low birth weight, and postnatal TB.^{1,2} If left untreated, TB in pregnancy can result in maternal mortality rates up to 40 percent.³ Despite substantial clinical need for TB prevention and treatment, pregnant women remain neglected by research initiatives.

Researchers, regulatory authorities, and communities have reached consensus about the need to include pregnant women in TB research.⁴ Yet, systematic exclusion of pregnant women from research persists, even when the ratio of potential benefit to harm favors their inclusion.⁵ Despite their exclusion from research, pregnant women get TB and clinicians have to treat them. In the absence of evidence, clinicians are put in the difficult position of treating TB in pregnant women using regimens of both old and newer TB drugs without adequate guidance on dose adjustments, safety, or efficacy.

To improve the availability of information critically important to guiding the safe prevention and treatment of TB in pregnant and postpartum women, we appeal to the Task Force to investigate and recommend to the Secretary of Health and Human Services to:

1. Develop a registry to collect data on the incidence of adverse events among pregnant women treated for TB infection and disease and other indications. It can be modeled after the Antiretroviral Pregnancy Registry (APR) created in 1989 to address data issues among pregnant women with HIV and overseen by an Interagency Advisory Committee with members from the U.S. Centers for Disease Control and Prevention, Food and Drug Administration, and National Institutes of Health;
2. Work with regulatory authorities and legislators to craft regulatory policy or legislation as necessary to codify the assessment of new therapies in pregnant and postpartum women, which can be enforced by regulatory authorities; and
3. Establish a mandate for research networks and institutions that receive funding from the U.S. government to put in place a standing protocol to, where appropriate, allow for the enrollment of pregnant women in the studies they conduct.

Respectfully submitted,

Organizations:

ACREOD
ACTION Global Health Advocacy Partnership
AIDS-Free World
American Thoracic Society (ATS)
Asian & Pacific Islander American Health Forum
Children's Hospital of Philadelphia
Eurasian Key Population Health Network (EKHN)
Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)
European AIDS Treatment Group (EATG)
Genesis Educational Trust
Global Coalition of TB Activists (GCTA)
Infectious Diseases Society of America (IDSA)
International Community of Women living with HIV Eastern Africa
International Health Consultancy, LLC
Jhpiego
JOPPA CENTRE
Kenya AIDS NGOs Consortium (KANCO)
Kigali Hope Association
Meera Foundation
National TB Controllers Association (NTCA)
New Jersey Association on Corrections
Pakistan Institute of Medical Sciences
Positive Women's Network - USA
Red Ribbon Istanbul
RESULTS
RESULTS International Australia
Socios En Salud (SES)
TB Proof
Treatment Action Group (TAG)
World Foundation for Medical Research and Prevention

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¹ Loto OM, Awowole I. Tuberculosis in pregnancy: a review. *J Pregnancy* 2012; 2012: 379271.

² Jana N, Barik s, Arora N, et al. Tuberculosis in pregnancy: the challenges for South Asian countries. *J Obstet Gynaecol Res.* 2012; 38(9): 1125–36.

³ Mathad JS, Gupta A. Tuberculosis in pregnant and postpartum women: epidemiology, management, and research gaps. *Clin Infect Dis.* 2012; 55: 1532–49.

⁴ Gupta A, Mathad JS, Abdel-Rahman SM, et al. Towards earlier inclusion of pregnant and postpartum women in TB drug trials: consensus statements from an international expert panel. *Clin Infect Dis.* 2015. doi: 10.1093/cid/civ991.

⁵ McKenna L, Frick M, Lee C, et al. A community perspective on the earlier inclusion of pregnant women in TB drug trials. *Clin Infect Dis.* 2017. doi: <https://doi.org/10.1093/cid/cix533>.