

WE NEED A REGISTRY FOR TUBERCULOSIS MEDICINES IN PREGNANCY

In 2015, there were an estimated 10.4 million new cases of tuberculosis (TB) globally. Of these, 3.5 million were women.¹ Figures for the incidence of TB among pregnant women are not currently reported at the global level, but an estimated 216 million women get pregnant each year, a majority of which reside in low- and middle-income countries where TB remains prevalent.²

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.^{3,4} If left untreated, TB in pregnancy can result in maternal mortality rates up to 40 percent.⁵ Despite substantial clinical need for TB prevention and treatment options, 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.⁶ Yet, systematic exclusion of pregnant women from research persists, even when the ratio of potential benefit to harm favors their inclusion.⁷ 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.

These persisting gaps in our knowledge can be addressed using a registry modeled after that used to monitor the use of HIV medications in pregnant women.⁸ Data collected through the Antiretroviral Pregnancy Registry (APR) created in 1989 has been critical to informing the safe and effective treatment of pregnant women with HIV. A similar registry for TB medicines to collect data on the incidence of adverse events among pregnant women treated for TB infection and disease and their infants, would provide information important to guiding safe TB prevention and treatment. A pregnancy registry for TB medicines is especially vital given the lack of data, and few ongoing or planned TB studies inclusive of pregnant women.⁹

A registry for pregnant women with TB would need to be publically funded and maintained. The APR is sponsored and maintained by the pharmaceutical industry, but there are few companies investing in TB drug research given the lack of a market incentive for doing so. As a result, a registry for pregnant women with TB can only be established with the support of public funding, and the community leadership of clinicians that care for pregnant and postpartum women and their infants.

HERE IS WHAT YOU CAN DO TO HELP

Put the need for more TB data on the agenda of the newly formed Taskforce on Research Specific to Pregnant Women and Lactating Women. This taskforce is charged with advising the Secretary of the U.S. Department of Health and Human Services on Federal activities related to identifying and addressing gaps in knowledge about therapies for pregnant and lactating women. **Here's what you can do:**

****Endorse the open letter available at the following link:**

<http://www.treatmentactiongroup.org/TBPregSignon>

****Share and talk about this brief with your peers. This brief is available online at the following link:**

<http://www.treatmentactiongroup.org/TBPregBrief>

****Stay informed on progress and take future action on this, and other important TB research issues, by joining TAG's Research Action Network: www.treatmentactiongroup.com/tb**

****For more information, please write to Lindsay.McKenna@treatmentactiongroup.org**

¹ World Health Organization. Global tuberculosis report 2016. Available from: <http://www.who.int/tb/publications/glr>

² World Health Organization. Global Health Observatory (GHO) data: Maternal mortality trends [Internet]. Available http://www.who.int/gho/maternal_health/mortality/maternal/en/index2.html.

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- ⁴ 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.
- ⁵ Mathad JS, Gupta A. Tuberculosis in pregnant and postpartum women: epidemiology, management, and research gaps. *Clin Infect Dis.* 2012; 55: 1532–49.
- ⁶ 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.
- ⁷ 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>.
- ⁸ The antiretroviral pregnancy registry. For health care providers [Internet]. Available from: <http://www.apregistry.com/HCP.aspx>.
- ⁹ McKenna, L. TB research updates for pregnant women. In: 2017 Pipeline Report; The tuberculosis diagnostics and treatment pipeline for children. Treatment Action Group. Available from: <http://www.pipelinerreport.org/sites/default/files/2017-Pipeline-Report-PEDS.pdf>.