August 17, 2017

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

Treatment Action Group's Comments for the Task Force on Research Specific to Pregnant and Lactating Women

Dear Ms. Kaeser,

Thank you to you and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) for organizing this meeting.

Below, please find a hard copy of the comments I will present to the Task Force on Research Specific to Pregnant and Lactating Women on Tuesday, 21 August 2017.

Sincerely,

/Lindsay McKenna/

Lindsay McKenna, MPH
Senior TB/HIV Project Officer
Treatment Action Group

Treatment Action Group's Comments to the Task Force on Research Specific to Pregnant and Lactating Women

Thank you to the the Eunice Kennedy Shriver National Institute of Child Health and Human Development for organizing this meeting and to the Task Force for its commitment to finding solutions for pregnant women and the clinicians charged with their care, and for allowing this opportunity for the public to offer our perspectives. I will be focusing my comments on research for pregnant women with tuberculosis (TB).

I'm Lindsay McKenna and I work at Treatment Action Group (TAG), an independent, activist and community-based research and policy think tank that has been fighting for better treatment, prevention, diagnosis, a vaccine, and a cure for HIV for 25 years, and for TB, and hepatitis C virus for over 10 years.

TAG first became engaged in issues related to pregnancy and research while reviewing clinical trials protocols for TB drugs and regimens. We noticed over and over again identical language used to exclude pregnant women from research, even when the ratio of potential benefit to harm favored their inclusion in trials.

Recognizing that in the absence of evidence, clinicians are put in the difficult position of treating pregnant women with medicines without adequate guidance on dose adjustments, safety, or efficacy; and the risks and burden of anxiety this creates for women who require treatment while pregnant, we have been working to challenge this assumption that pregnant women cannot be safely and ethically included in research.[1]

The International Maternal Pediatric Adolescent AIDS Clinical Trials network (IMPAACT), which is funded by the U.S. National Institutes of Health (NIH), is a great example of how this can be done. You will hear more about the IMPAACT network in Dr. Nachman's remarks.

IMPAACT, along with the four other clinical research networks (the AIDS Clinical Trials Group [ACTG], HIV Prevention Trials Network [HPTN], HIV Vaccines Trials Network [HVTN], and Microbicide Trials Network [MTN]) under the NIH Division of AIDS (DAIDS), will be up for re-competition in 2020. DAIDS is soliciting feedback now for how these networks should be structured and what scientific questions they should aspire to answer. I encourage the Task Force to engage with DAIDS leadership on this subject to reinforce the importance of the IMPAACT network and the infrastructure and expertise it has built to facilitating future research in pregnant and postpartum women.

TAG's efforts and thinking around research and pregnancy have been focused in the context of TB and HIV, but the ideas we have for how to close data gaps for pregnant women have potential to benefit women with or at risk of other diseases and infections as well.

We'd like to appeal to the Task Force to further investigate and consider including the following among its recommendations to the U.S. Secretary of Health and Human Services (HHS) for how the federal government can help address gaps in research and knowledge for pregnant and postpartum women:

1. Develop an international registry to collect data on the incidence of adverse events among pregnant women treated for TB 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;
2. Establish a mandate for research networks, institutions, and investigators 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; and
3. 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.

Prioritization of diseases on which the task force and the federal government will focus efforts and investments is inevitable. In closing, I encourage the Task Force to ensure that its priorities are not determined solely by the burden of disease in the U.S., which would leave out diseases like zika, ebola, and tuberculosis, but also in terms of existing and emerging threats to global health security, which will inevitably affect U.S. citizens, including antimicrobial resistance (AMR).

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[1] McKenna L, Frick M, Lee C, et al. A community perspective on the inclusion of pregnant women in TB drugs trials. Clin Infect Dis. 2017 June 16. doi: https://doi.org/10.1093/cid/cix533.