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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).