Experts, advocates publish guidance for research on HIV, co-infections in pregnancy

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Pregnant women are among those most in need of safe and effective preventives and treatments for HIV and co-infections. Yet because they are commonly excluded from research, they are among the least likely to

have robust, timely evidence to inform decisions around the use of medications.

"The resulting evidence gaps and delays are significant," said senior author and PHASES Principal Investigator Anne Drapkin Lyerly, MD, professor of social medicine at the UNC School of Medicine and associate director of the UNC Center for Bioethics, "and they put pregnant women and their children in harm's way. Ethically, we must work together to give pregnant women the evidence base they deserve."

Changing practices in the HIV/co-infections research community so that women, providers, and policy makers can make evidence-informed decisions around the use of medications during pregnancy is the goal of the new report, Ending the Evidence Gap for Pregnant Women around HIV and Co-infections: A Call to Action, issued today by the Pregnancy and HIV/AIDS: Seeking Equitable Study (PHASES) Working Group—an international and interdisciplinary team of 26 experts in bioethics, public health, law, obstetrics and maternal-fetal medicine, pediatrics, HIV research, infectious disease, and pharmacology, as well as community advocates for women living with HIV.

Led by faculty at the University of North Carolina School of Medicine, Georgetown University, and Johns Hopkins University, the PHASES Project—with funding from the U.S. National Institutes of Health—conducted extensive research with affected women and engagement with the HIV research community to inform the report. The guidance, presented this week at the AIDS 2020: Virtual conference, has been endorsed by the International Community of Women Living with HIV Global and East Africa.

"The HIV research and advocacy communities have increasingly recognized the importance of protecting pregnant women through responsible research. But there are still a lot of misconceptions and other

barriers to doing this work. Our guidance aims to clear an ethical pathway forward for research to improve the health and safety of women and the children they bear," said Lyerly.

The guidance puts forth 12 concrete, actionable recommendations, which include:

- Formalize a global network for advocacy and resources. The global HIV/co-infections research and advocacy communities, supported by funders, should formalize a network to develop and share a portfolio of resources to empower the HIV research community to advance needed research with pregnant women.
- Design for inclusion. Researchers designing trials addressing HIV/co-infections should integrate pregnant women wherever possible and optimize opportunities to gather pregnancy-specific data.
- Ensure equitable research on pregnant women's own health. Agenda setters in HIV/co-infections research should commit to promoting the study of pregnant women's own health needs as a key pillar of effort and funding. Research into fetal safety outcomes should be matched by relevant maternal outcomes assessments.
- Enhance post-approval safety evaluations. The HIV/co-infections research community should commit to a more robust and regularized structure of postapproval safety evaluations to ensure both adequate pharmacovigilance and pregnant women's timely access to important drugs.
- Contextualize risk findings. Those conducting HIV/co-infections research with pregnant women should anticipate possible adverse events and proactively develop communication strategies for adequately contextualizing them against baseline rates of such events. Communication of overall findings should contextualize potential risks of an intervention against its potential benefits and

the risk-benefit profiles of alternatives.

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