HIV TREATMENT

MEETING REPORT

APPROACHES TO ENHANCE AND ACCELERATE STUDY OF NEW DRUGS FOR HIV AND ASSOCIATED INFECTIONS IN PREGNANT WOMEN

DECEMBER 2021

World Health Organization

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International Maternal Pediatric Adolescent AIDS Clinical Trials Network

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The WHO and the IMPAACT Network facilitated a workshop, Approaches to Enhance and Accelerate Study of New Drugs for HIV and Associated Infections in Pregnant Women, aimed at gaining consensus on the optimal timing and design of studies of new drugs for treating and preventing HIV and related conditions among pregnant women. This workshop brought together women living with HIV, academic researchers, clinical experts, regulators, industry leaders, funders and other key stakeholders involved in studying HIV-related drugs for pregnant women. The workshop was held virtually on 8-10 December 2020 (part 1) and 6-7 July 2021 (part 2).

BACKGROUND

With more than 19 million women living with HIV worldwide – most of whom are of childbearing potential – there is a public health imperative to ensure that they can make informed choices about the drugs they take for HIV treatment or prevention. Information to support optimal antiretroviral drug choices in pregnancy has rarely been available for women or their health-care providers, largely because of historically protectionist and conservative approaches to clinical studies conducted among pregnant and breastfeeding women.

Pregnant and breastfeeding women are usually excluded from clinical trials of new agents (pre- and post-licensure). In addition, women of childbearing potential are typically underrepresented in pre-licensure drug trials and are usually required to use dual contraception to participate. Further, those who become pregnant while participating must discontinue the study drug. Therefore, pregnancy safety and pharmacokinetic data for new drugs are routinely delayed by as much as a decade after initial drug approval if studies are performed at all. This results in substantial delays in women accessing new and better drugs. Additionally, despite the lack of data, these new drugs are prescribed for women of childbearing potential who become pregnant as well as for pregnant women. This results in women having to make decisions about using new agents without adequate information about dosing or safety in pregnancy. This lack of information from trials to guide pregnant women in using antiretroviral drugs shifts the burden of potential risk around drug safety from the clinical trial setting in which safety outcomes are carefully monitored to the real-world clinical care setting in which safety outcomes are not systematically captured.

Multiple agencies and actors have voiced their concerns around the exclusion of pregnant women from clinical trials and the associated harm and risks of these policies. More recently, the importance of allowing pregnant women the opportunity to take part in clinical trials has received renewed attention during the COVID-19 pandemic. Recognizing the urgency of addressing this issue, the IMPAACT Network and WHO held a workshop to refine optimal approaches to studying the safety and efficacy of new HIV-related drugs during pregnancy and to establish the next steps for creating materials and methods that would support the implementation of such studies.

OBJECTIVES

The overall objectives of the workshop were:

- to refine key principles around optimal approaches to studying new drugs for HIV (treatment or prevention) and associated infections in pregnant women: develop a framework for setting priorities, accelerating and optimizing the type and timing of studies involving pregnant women;
- to review and refine best practices on how to include pregnant women in studies of new drugs that are in Phase 3 studies for non-pregnant individuals; and
- to formulate a strategic action plan for promoting the inclusion of pregnant women in research on new HIV treatment and prevention drugs before drug regulatory authorization.

METHODS

The workshop co-convened by WHO and the IMPAACT Network brought together more than 100 participants from across the world, including women living with HIV, academic researchers, clinical experts, regulators, industry representatives, funders and other key stakeholders involved in studying drugs for the prevention and treatment of HIV and other infectious diseases among pregnant women. Organizations represented included WHO, IMPAACT, University of Geneva, HIV i-Base, Paediatric Antiretroviral Working Group, PANGEA, International AIDS Society, pharmaceutical companies involved in developing HIV agents, United States Food and Drug Administration, European Medicines Agency, Special Programme for Research & Training in Tropical Diseases, National Institute of Allergy and Infectious Diseases, Eunice Kennedy Shriver National Institute of Child Health and Human Development, Elizabeth Glaser Pediatric AIDS Foundation, Imperial College London, United States Agency for International Development, AIDS Clinical Trials Group, Microbicide Trials Network, Unitaid, HIV Prevention Trials Network, PHPT, Pregnancy and HIV/AIDS: Seeking Equitable Study, AfroCAB, Treatment Action Campaign, The Lancet, EUROmediCAT, RTI International, Medicines for Malaria Venture and many more including various academic institutions.

Fig.1 Outline of the workshop